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Asaad et al.

(10) **Patent No.: US 9,155,581 B2**
(45) **Date of Patent: Oct. 13, 2015**

(54) **STAGED LOCKING OF SURGICAL SCREW ASSEMBLY**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 479 days.

(21) Appl. No.: **13/717,599**

(22) Filed: **Dec. 17, 2012**

(65) **Prior Publication Data**

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Related U.S. Application Data

(63) Continuation-in-part of application No. 13/570,374, filed on Aug. 9, 2012.

(51) **Int. Cl.**

A61B 17/88	(2006.01)
A61B 17/86	(2006.01)
A61B 17/70	(2006.01)
A61B 19/00	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 17/88*** (2013.01); ***A61B 17/70*** (2013.01); ***A61B 17/7002*** (2013.01); ***A61B 17/708*** (2013.01); ***A61B 17/7032*** (2013.01); ***A61B 17/7034*** (2013.01); ***A61B 17/7035*** (2013.01); ***A61B 17/7037*** (2013.01); ***A61B 17/7038*** (2013.01); ***A61B 17/7049*** (2013.01); ***A61B 17/7079*** (2013.01); ***A61B 17/7085*** (2013.01); ***A61B 17/7091*** (2013.01); ***A61B 17/8605*** (2013.01); *A61B 2019/307* (2013.01)

(58) **Field of Classification Search**

CPC A61B 17/7032; A61B 17/7034; A61B 17/7035; A61B 17/7037; A61B 17/7038; A61B 17/8605; A61B 17/88

See application file for complete search history.

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Primary Examiner — Larry E Waggle, Jr.

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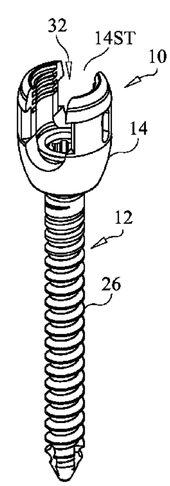
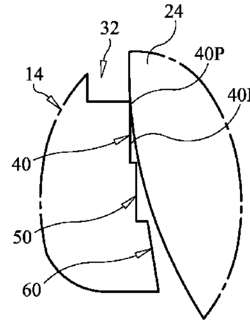
(57) **ABSTRACT**

A surgical screw assembly including: a fastener including an elongate shaft having a proximal end and a distal end and a head at the proximal end. A tulip having a an internal bearing surface is provided. A distal end of the tulip has a bore therethrough defining the internal bearing surface. Locking enhancement features are configured to cooperate with the head, such that, in an unlocked configuration, the head is movable relative to the tulip; in a provisionally locked configuration, the locking enhancement features engage the head with a first polyaxial grip strength; and in a finally locked configuration, the locking enhancement features engage the head with a second polyaxial grip strength greater than the first polyaxial grip strength.

22 Claims, 26 Drawing Sheets





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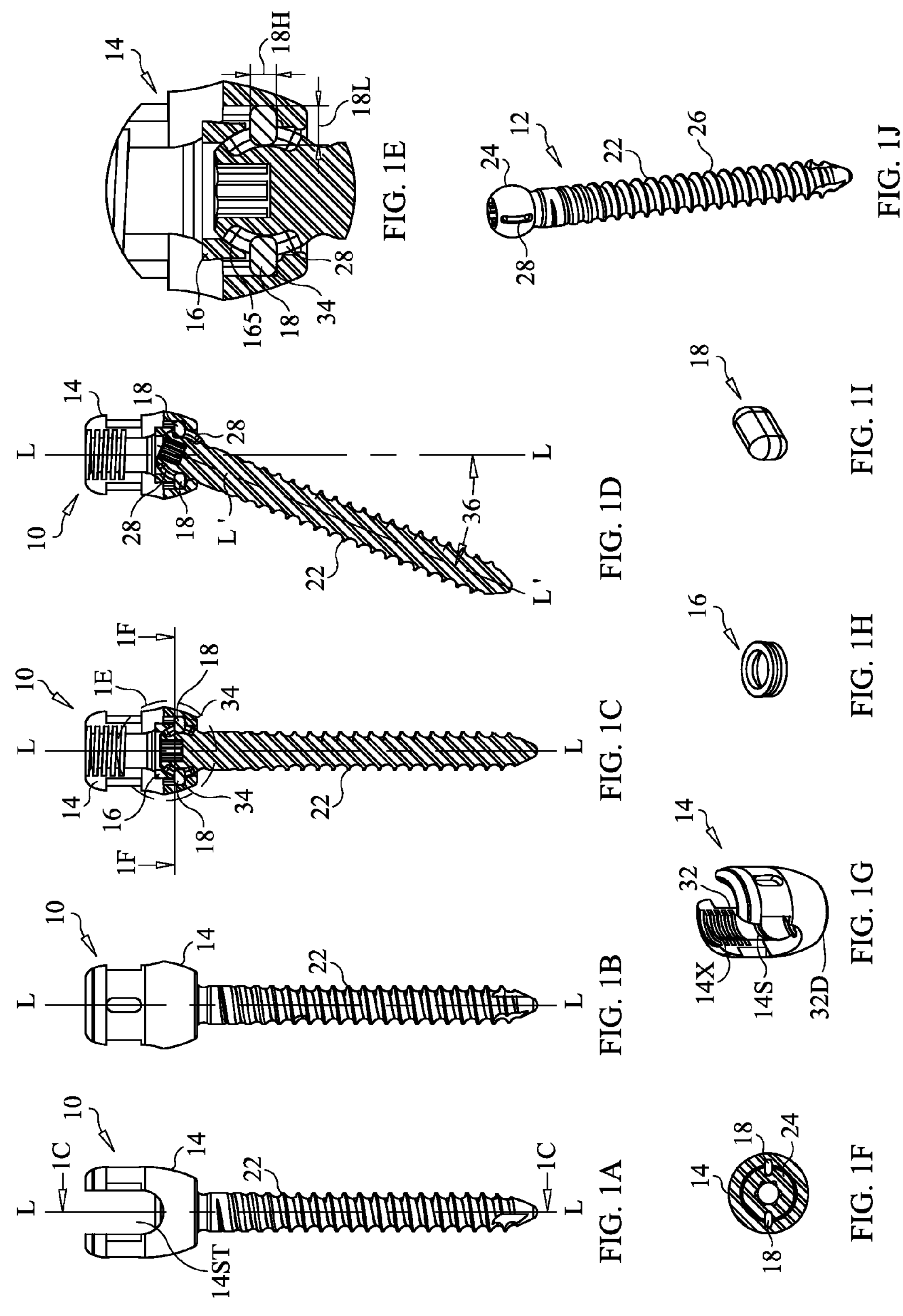
FIG. 1A
FIG. 1B
FIG. 1C
FIG. 1D
FIG. 1E
FIG. 1F
FIG. 1G
FIG. 1H
FIG. 1I
FIG. 1J
10
12
14
14ST
14X
14S
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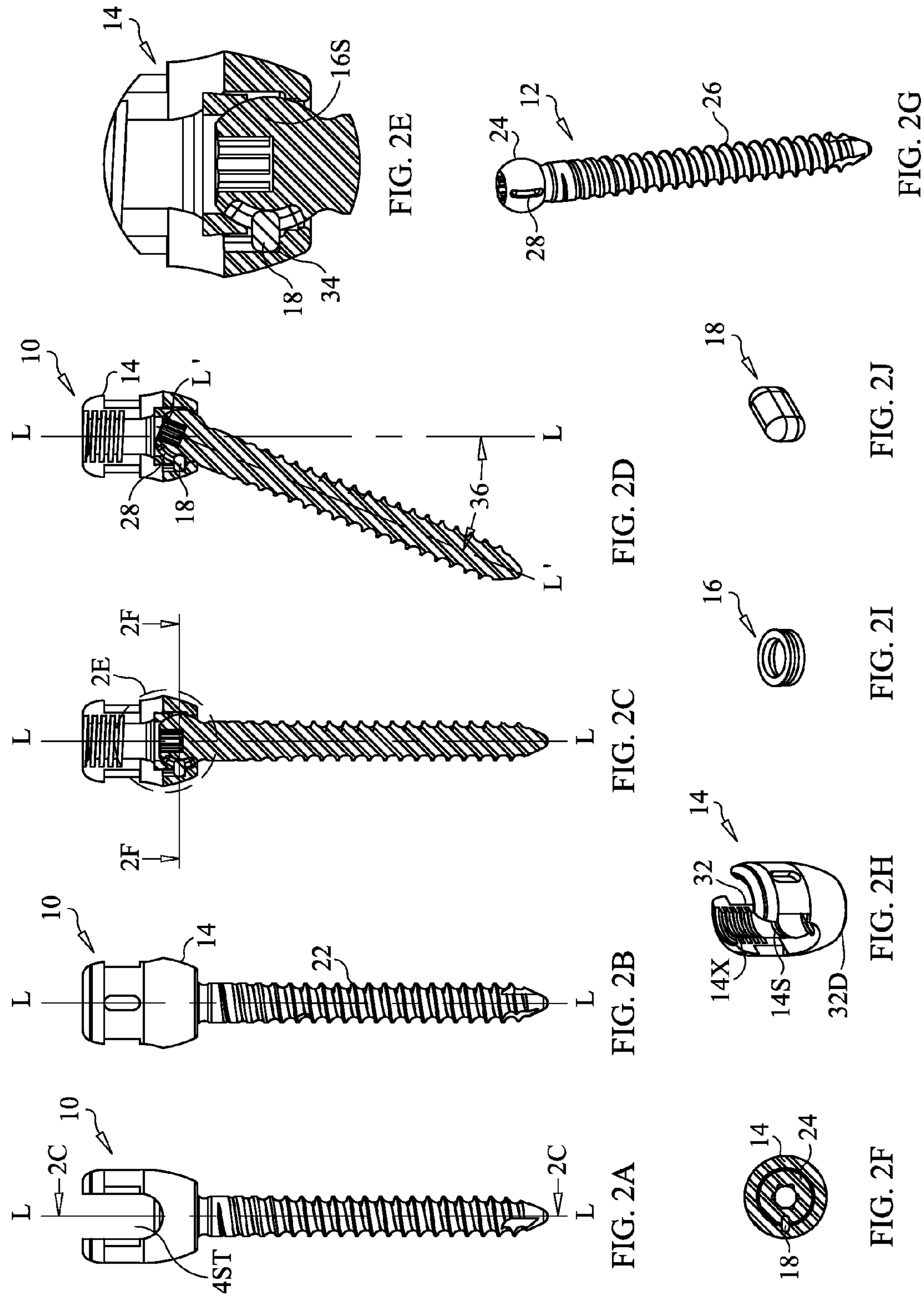

FIG. 2A FIG. 2B FIG. 2C FIG. 2D FIG. 2E FIG. 2F FIG. 2G FIG. 2H FIG. 2I FIG. 2J

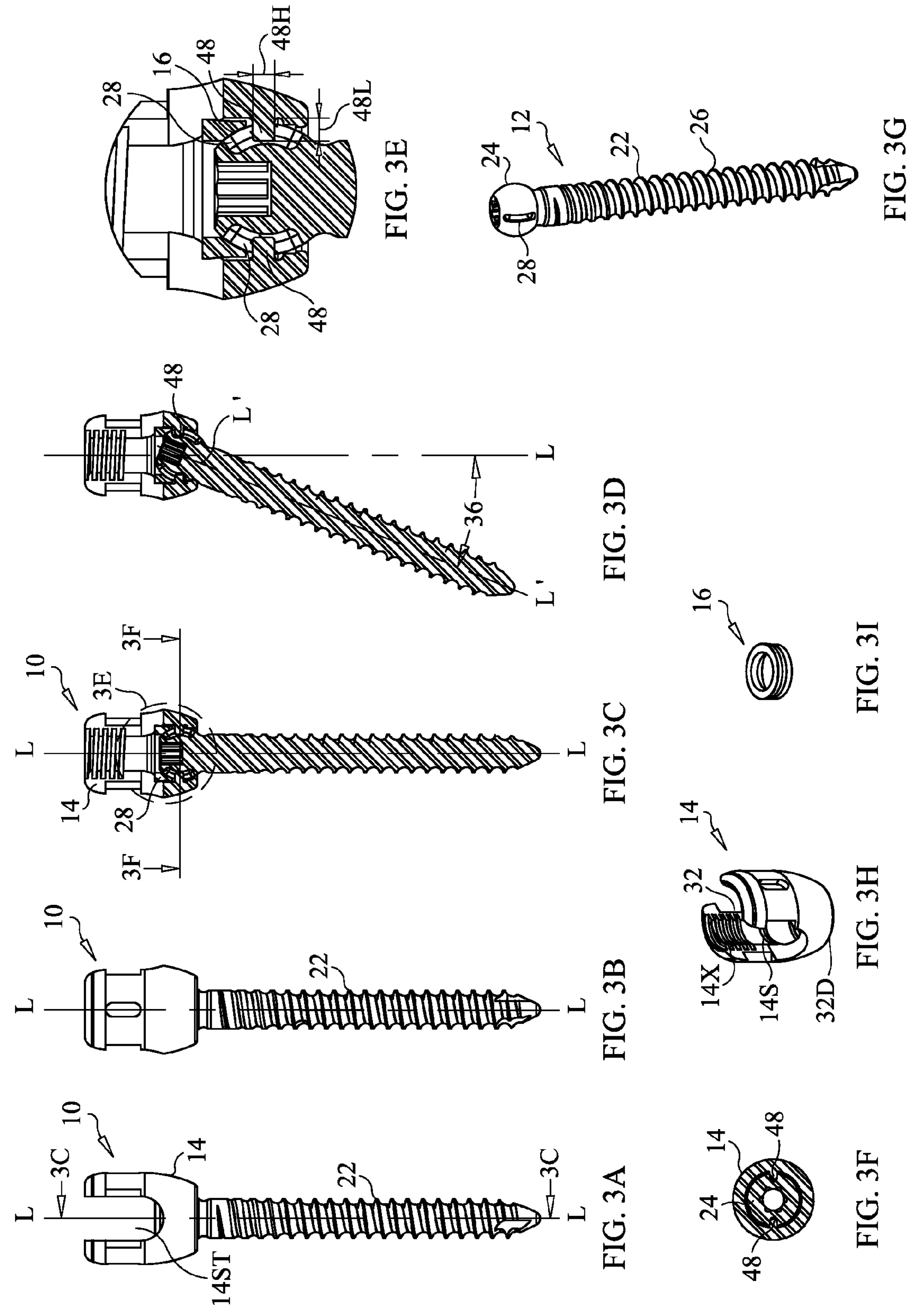

FIG. 3A
FIG. 3B
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FIG. 3G
FIG. 3H
FIG. 3I

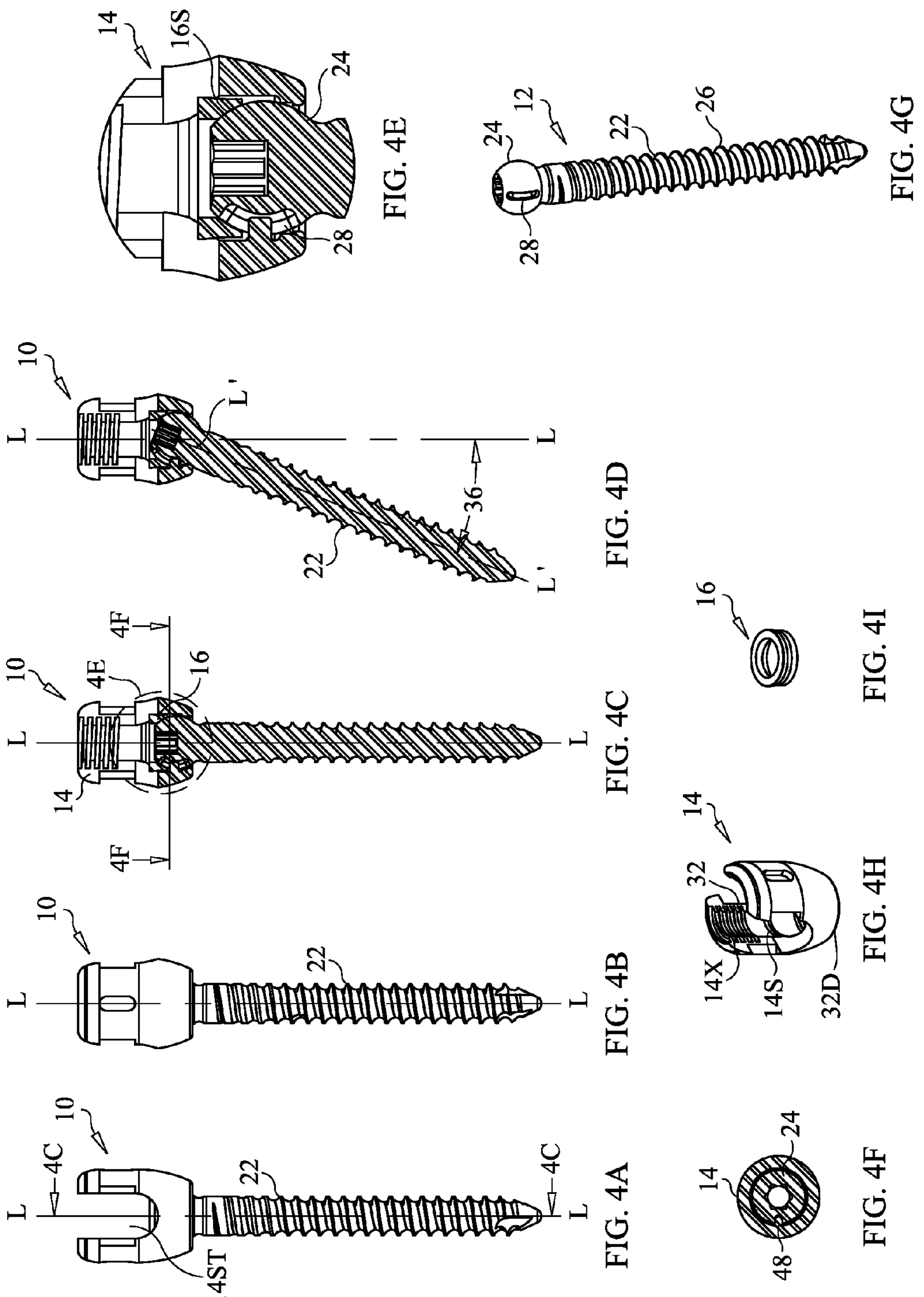

FIG. 4A

FIG. 4B

FIG. 4C

FIG. 4D

FIG. 4E

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FIG. 4G

FIG. 4H

FIG. 4I

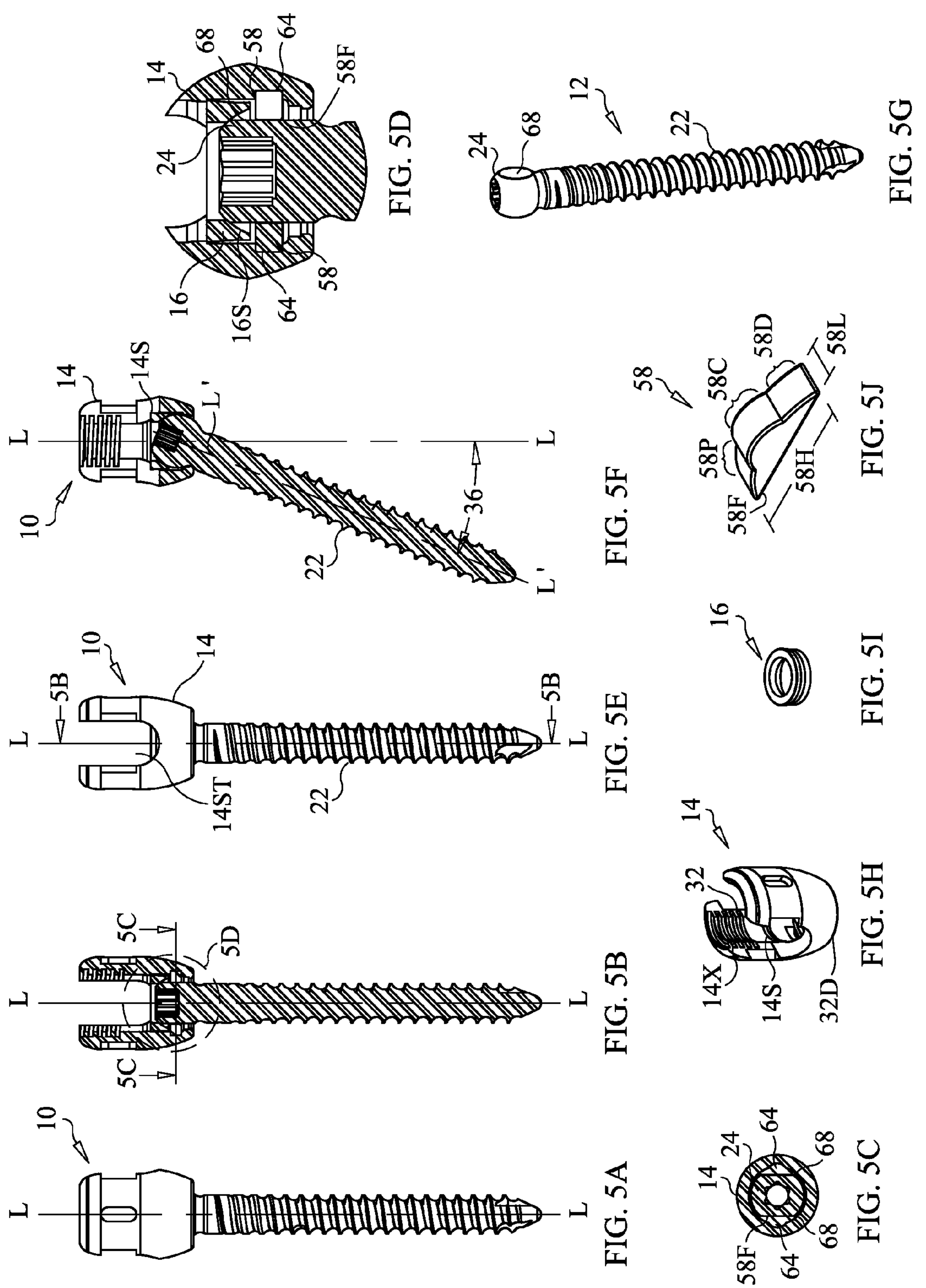

FIG. 5A

FIG. 5B

FIG. 5C

FIG. 5D

FIG. 5E

FIG. 5F

FIG. 5G

FIG. 5H

FIG. 5I

FIG. 5J

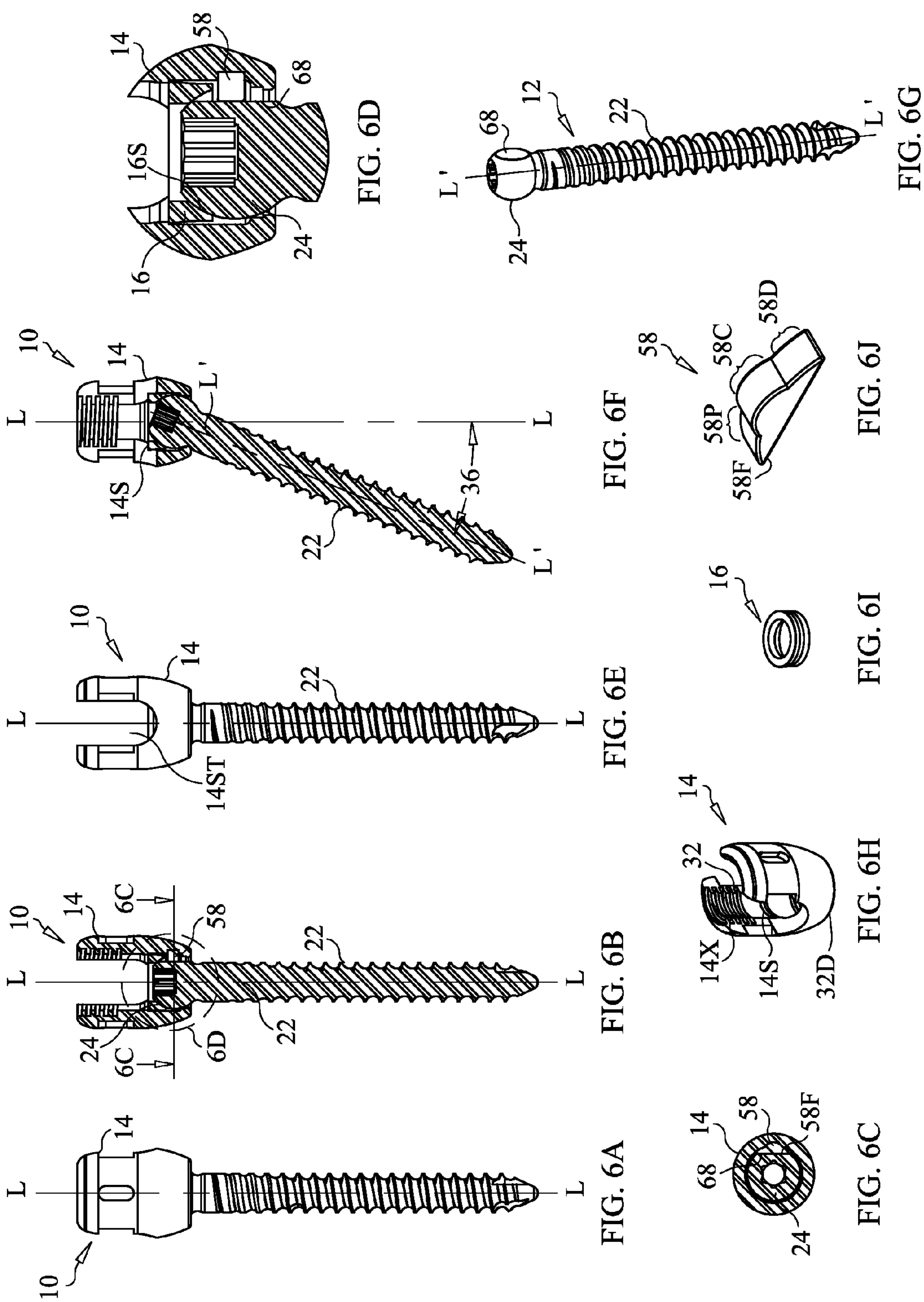

FIG. 6A

FIG. 6B

FIG. 6C

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FIG. 6F

FIG. 6G

FIG. 6H

FIG. 6I

FIG. 6J

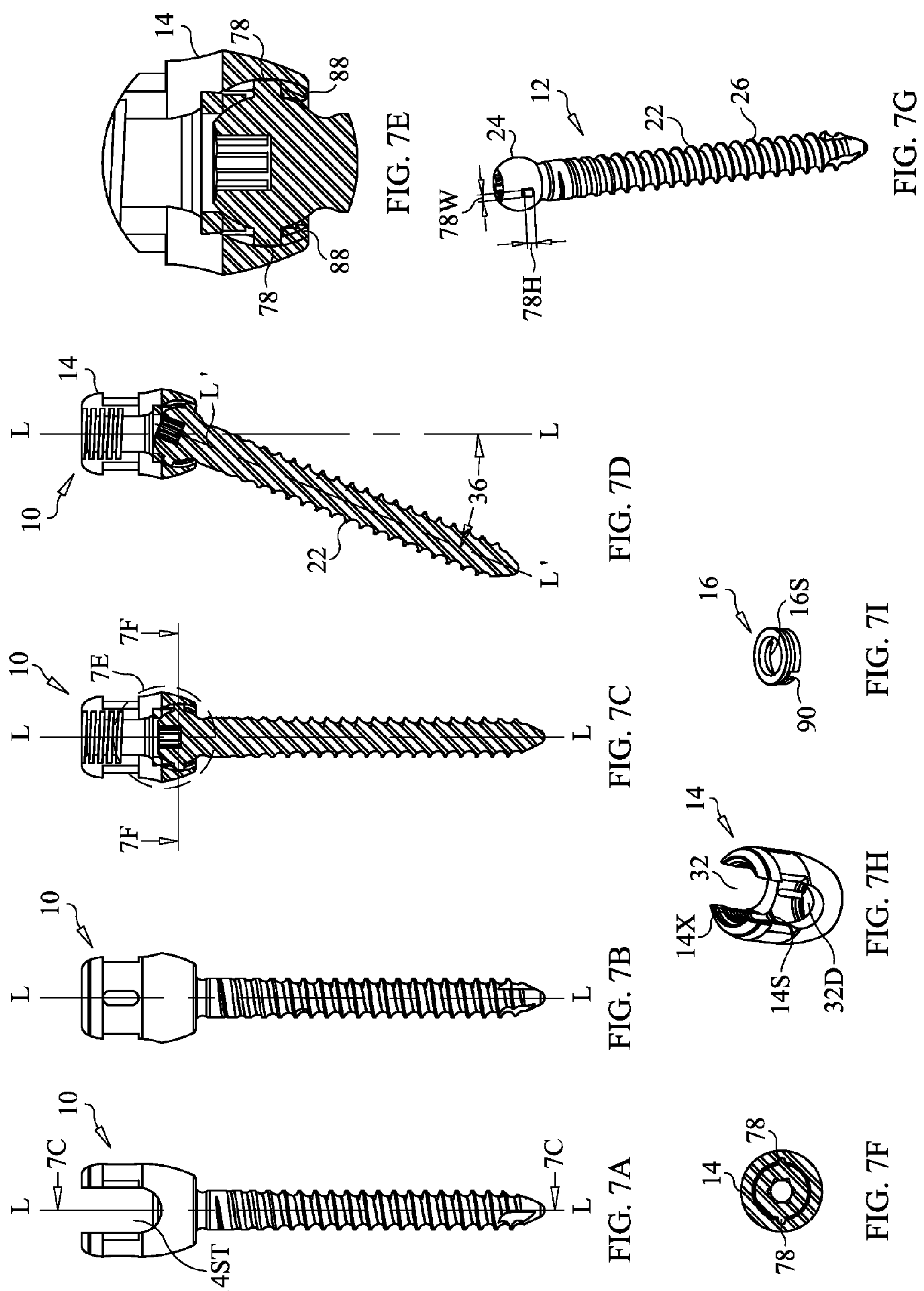


FIG. 7A FIG. 7B FIG. 7C FIG. 7D FIG. 7E FIG. 7F FIG. 7G FIG. 7H FIG. 7I

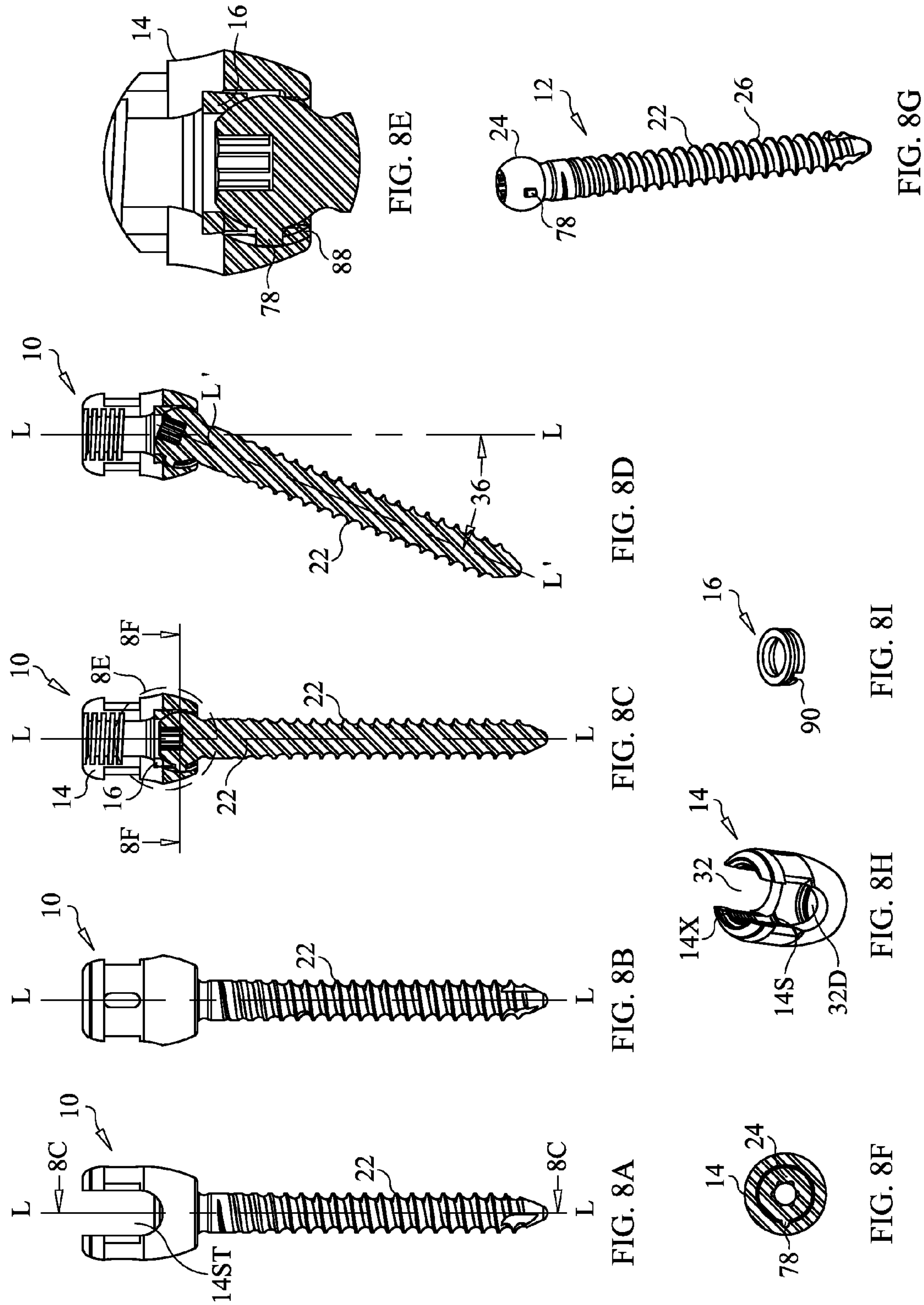


FIG. 8A

FIG. 8B

FIG. 8C

FIG. 8D

FIG. 8E

FIG. 8F

FIG. 8G

FIG. 8H

FIG. 8I

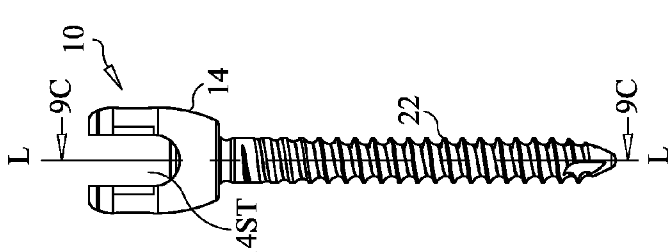
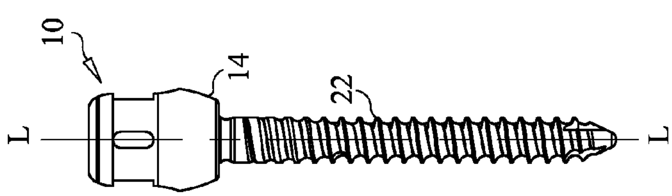


FIG. 9A



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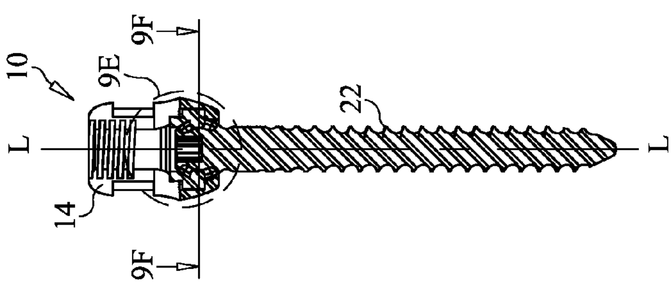
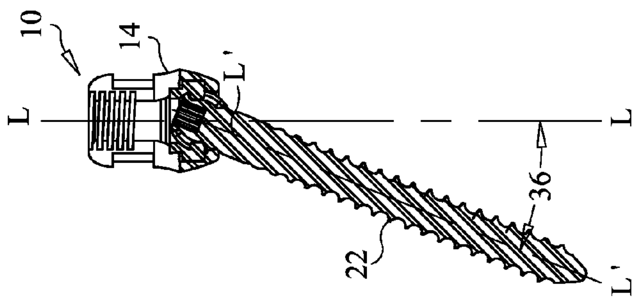


FIG. 9C



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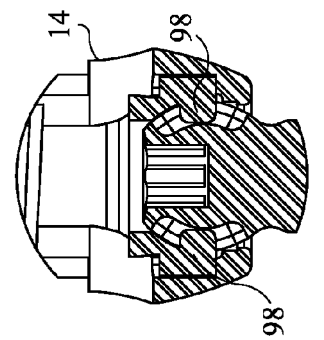

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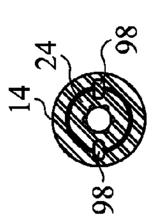

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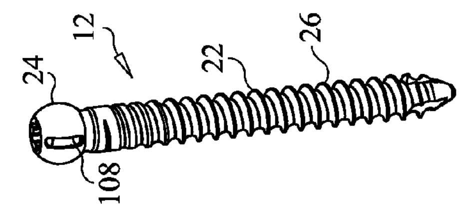

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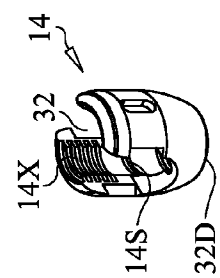

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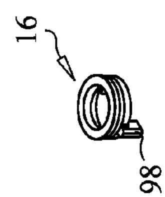

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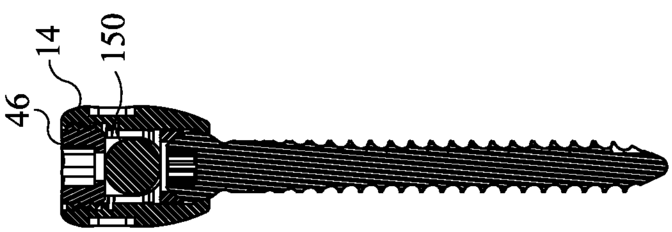

FIG. 10

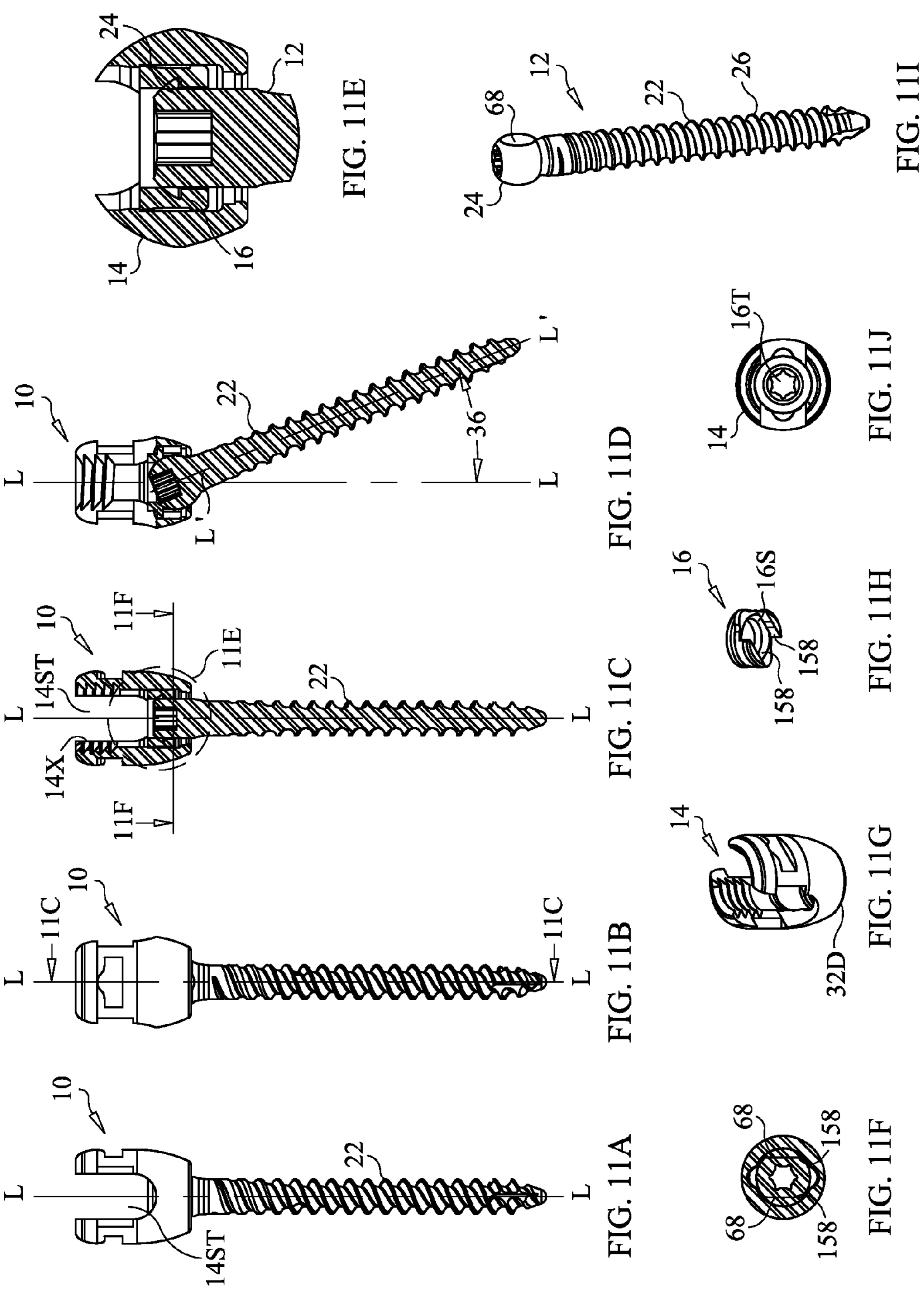

FIG. 11A
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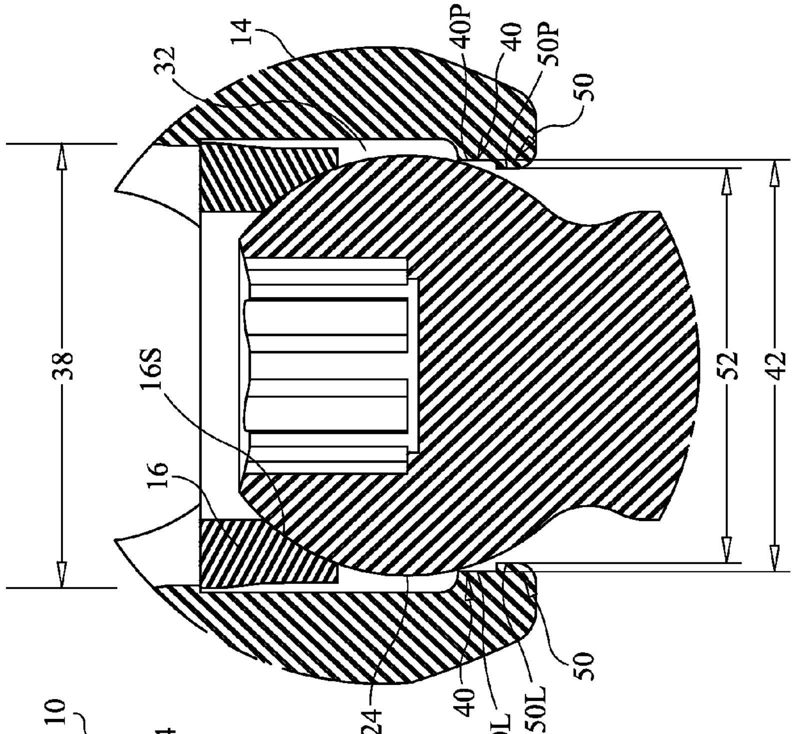
FIG. 11F
FIG. 11G
FIG. 11H
FIG. 11I
FIG. 11J



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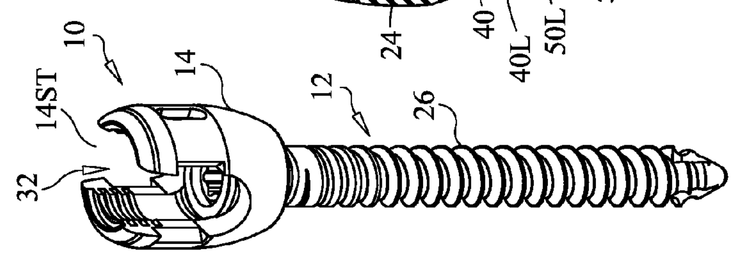

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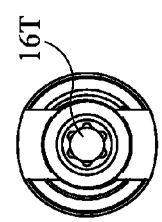
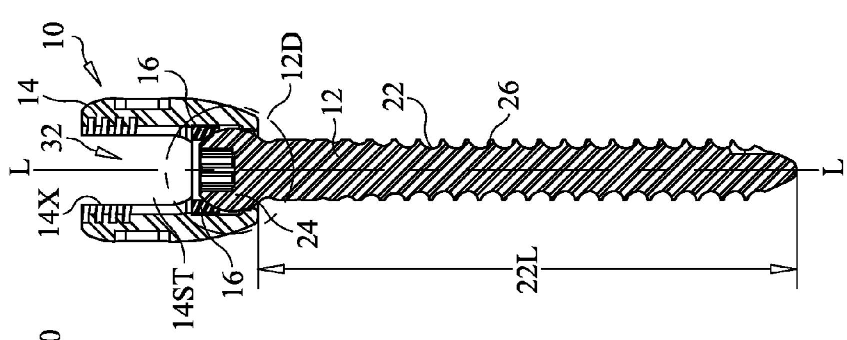


FIG. 12E



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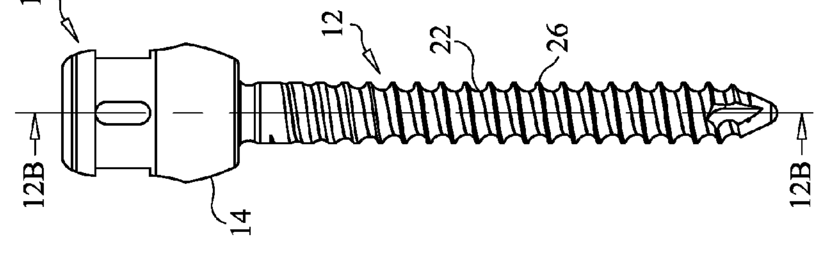

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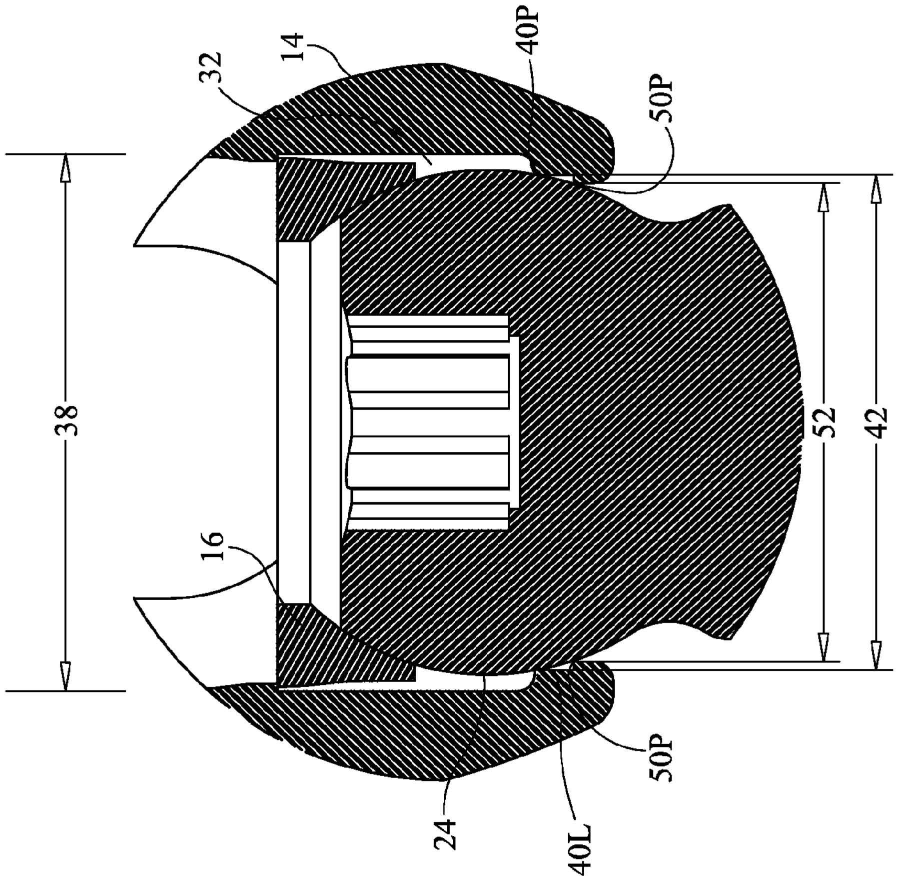


FIG. 12G

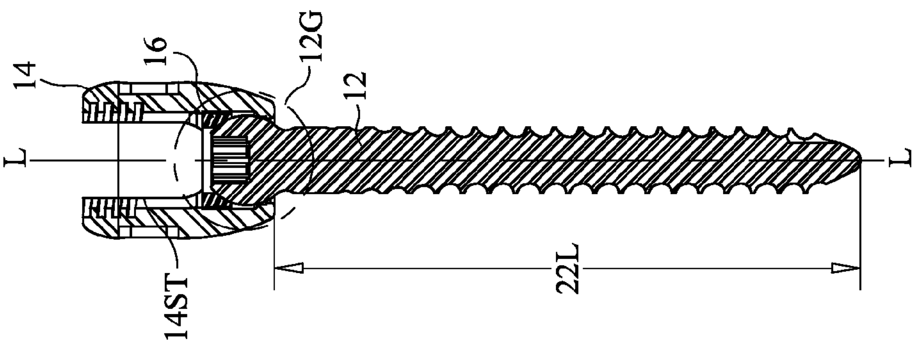


FIG. 12F

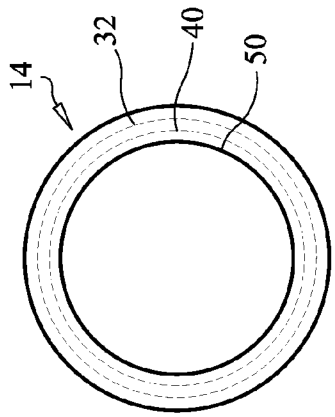


FIG. 12H

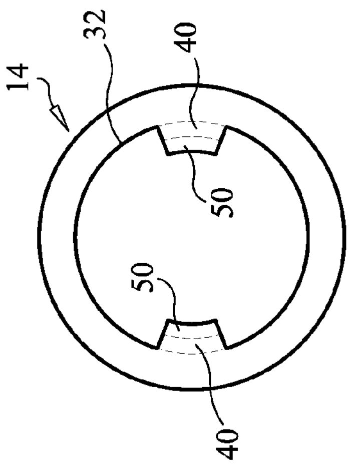


FIG. 12I

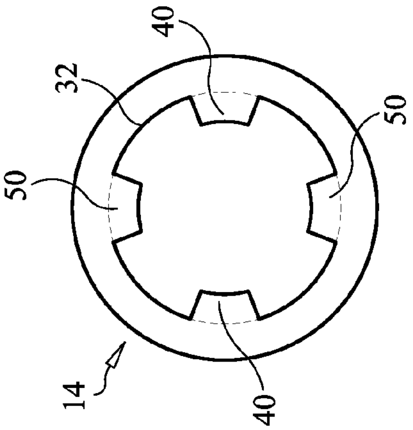


FIG. 12J

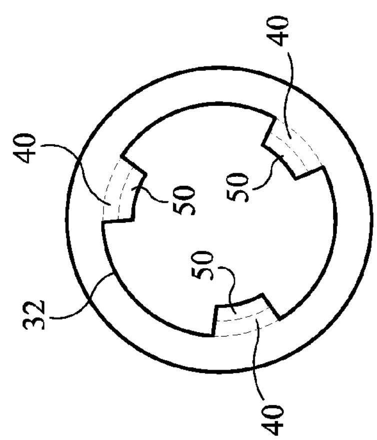


FIG. 12K

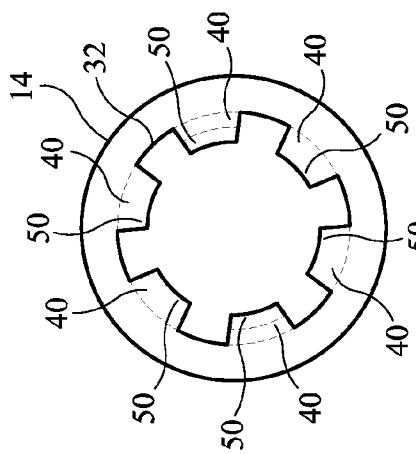
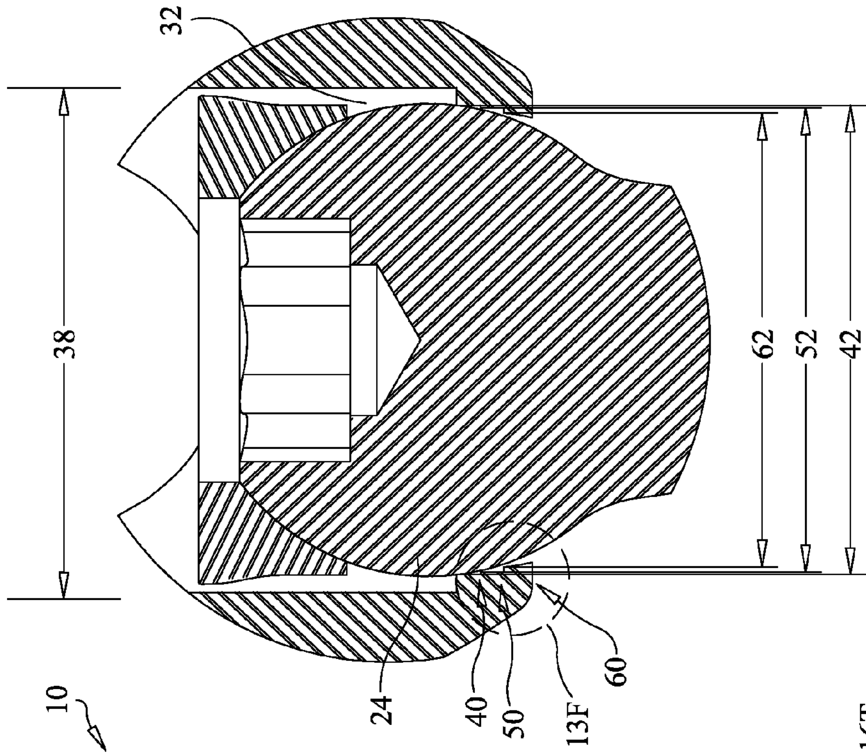


FIG. 12L



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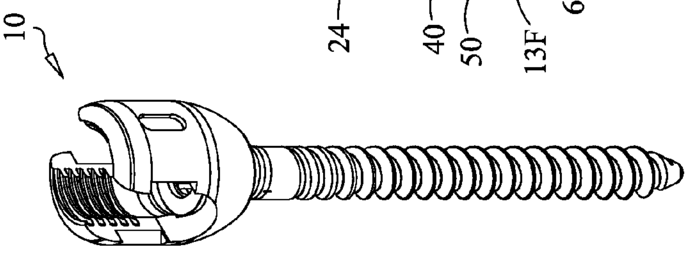

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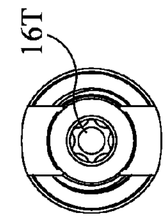

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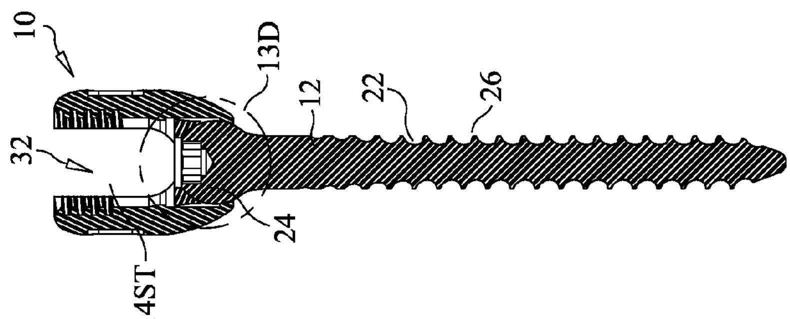

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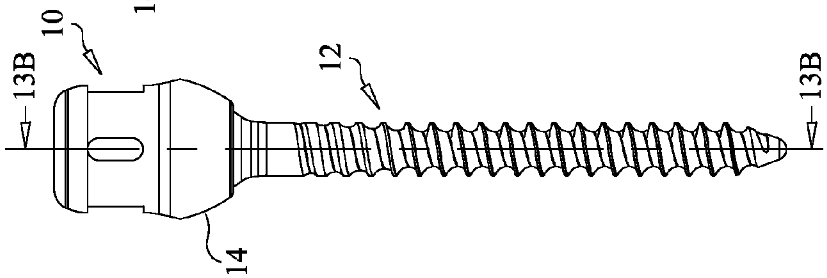


FIG. 13A

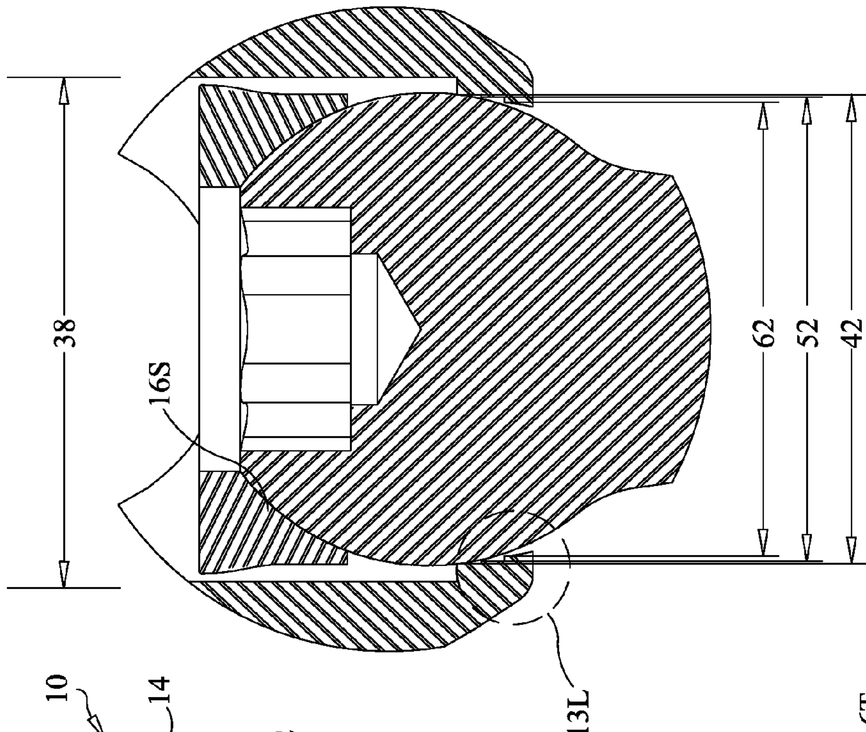


FIG. 13J

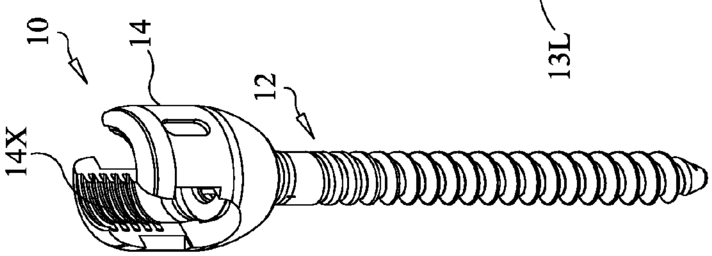


FIG. 13I

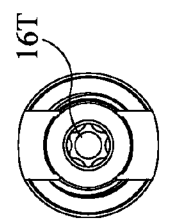


FIG. 13K

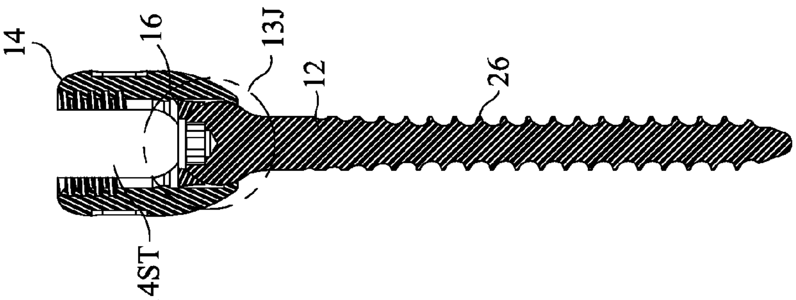


FIG. 13H

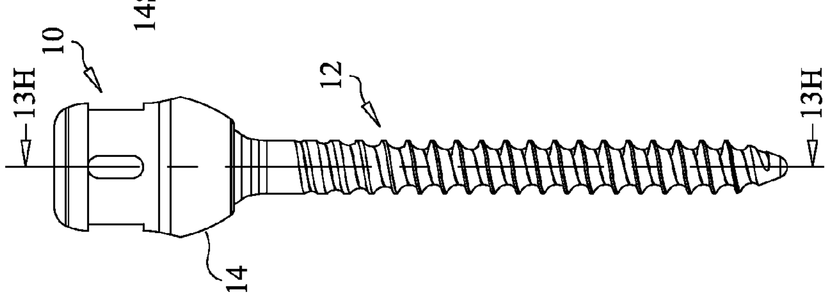
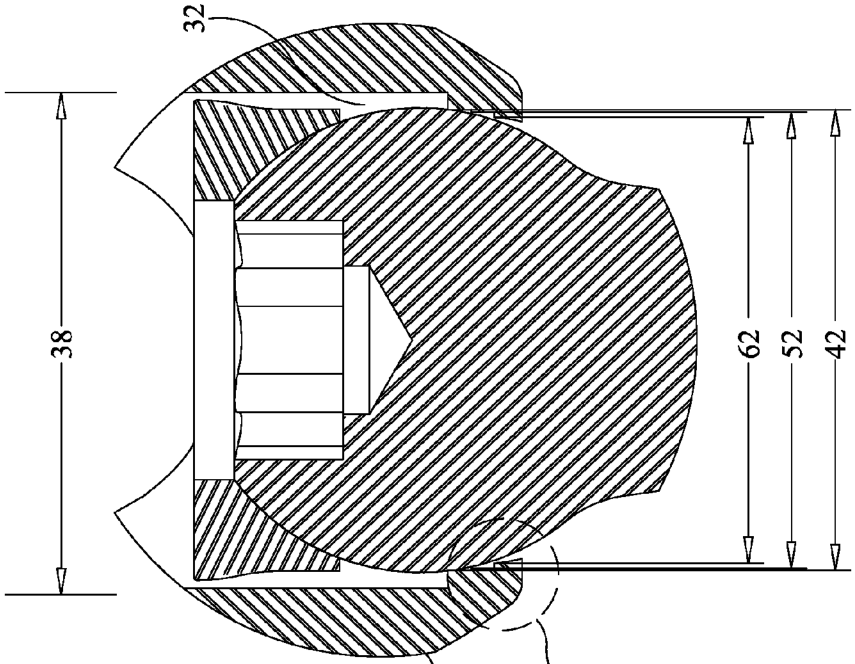


FIG. 13G



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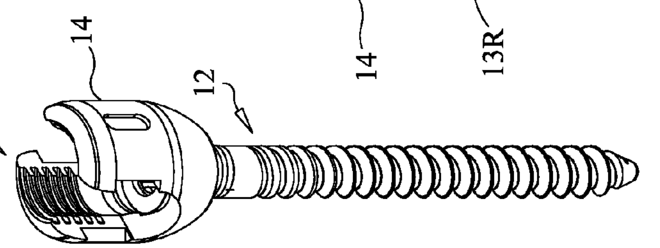

FIG. 13O

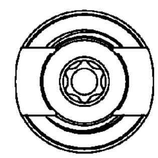

FIG. 13Q

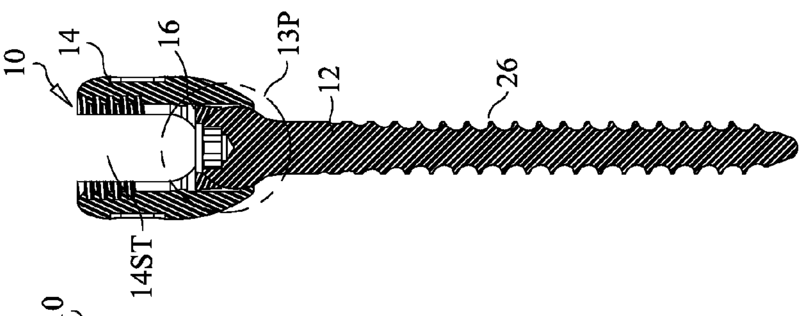

FIG. 13N

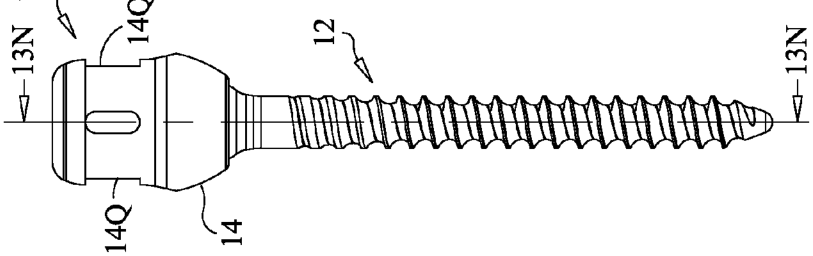

FIG. 13M

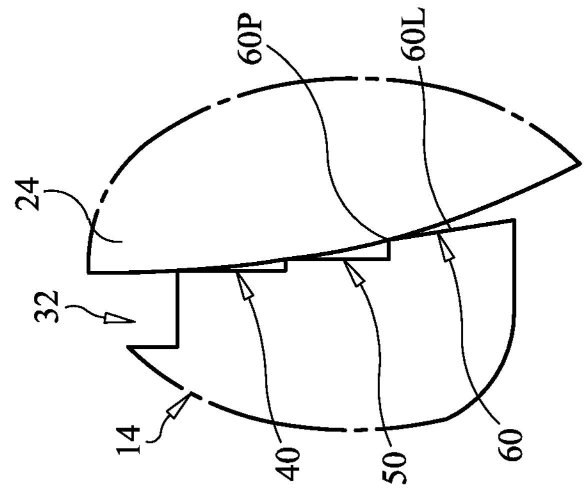

FIG. 13R

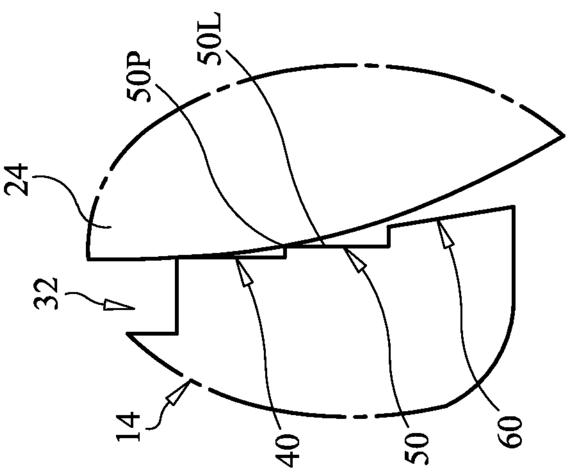

FIG. 13L

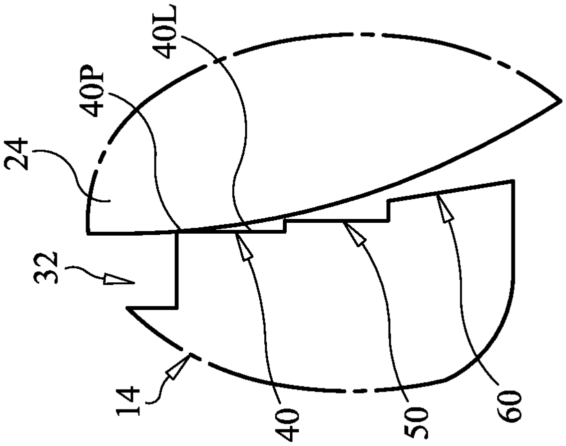

FIG. 13F

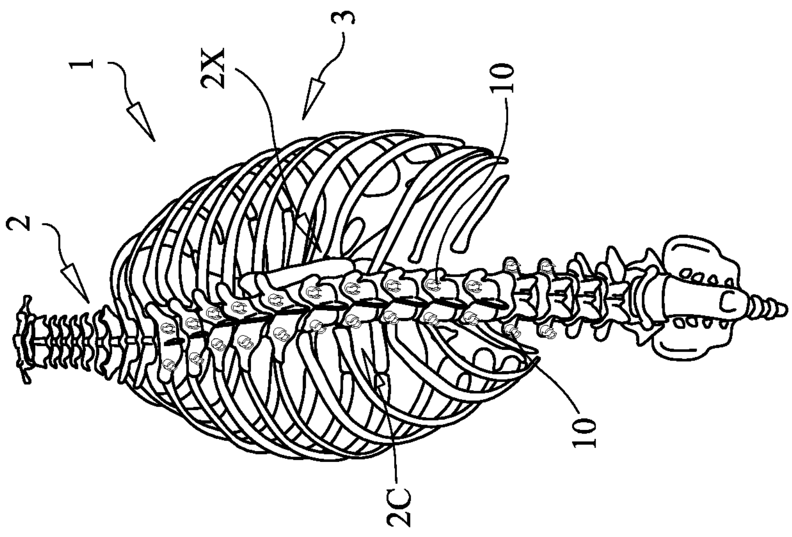

FIG. 14A

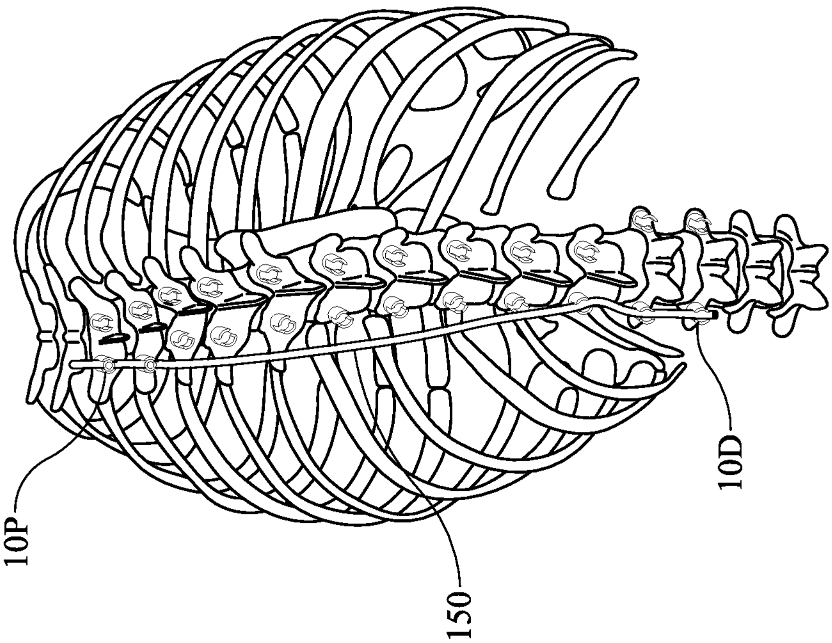

FIG. 14B

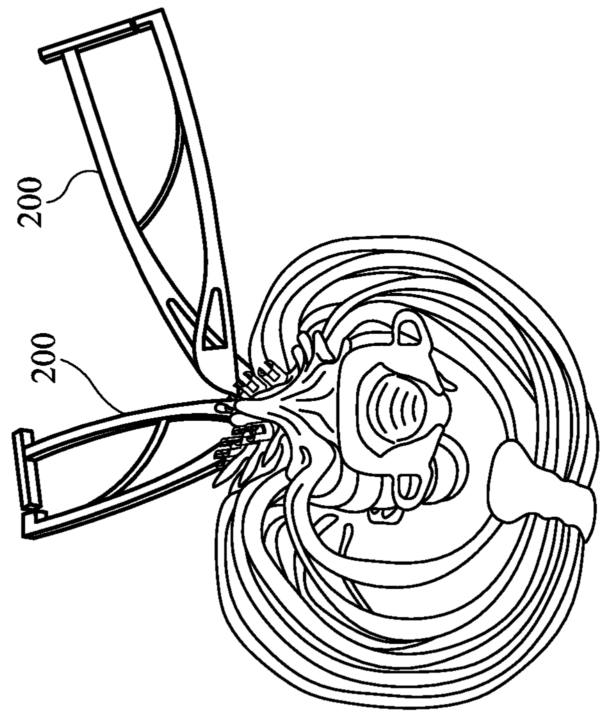

FIG. 14D

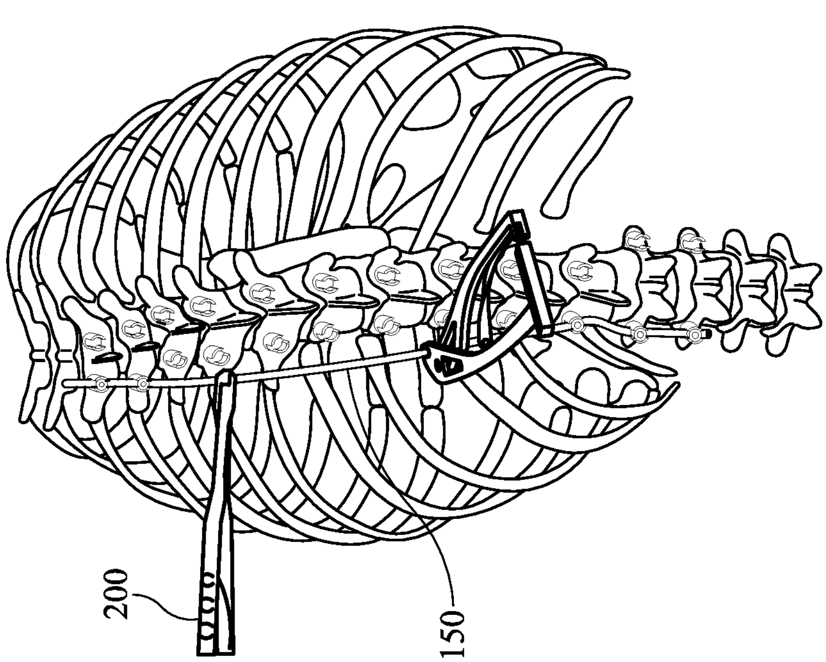

FIG. 14C

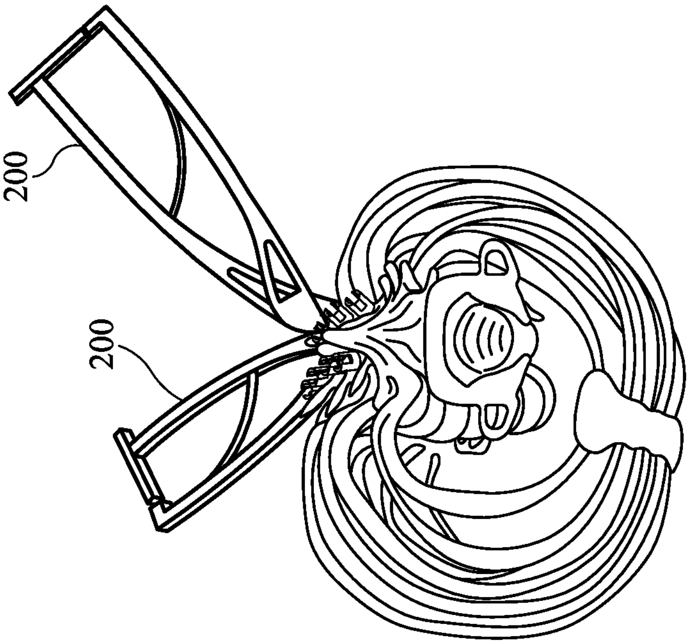

FIG. 14F

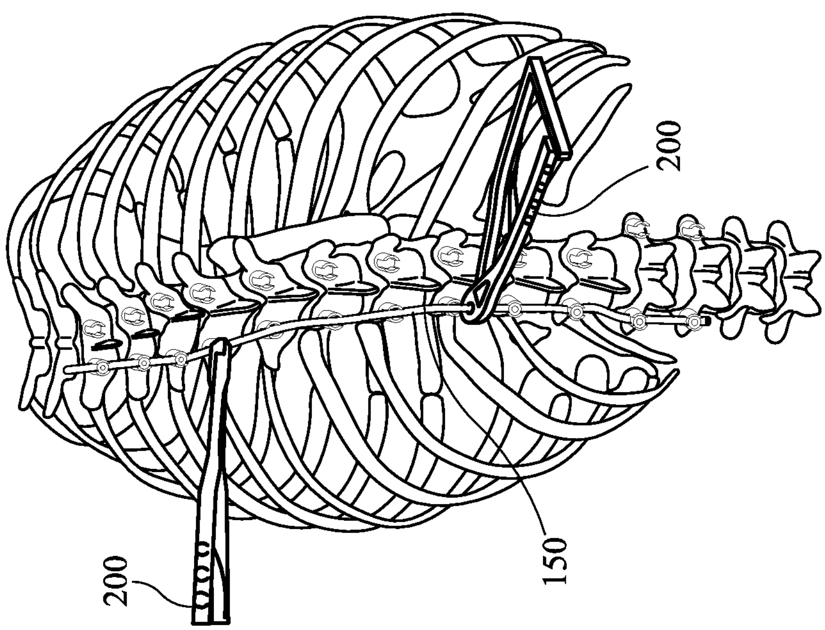

FIG. 14E

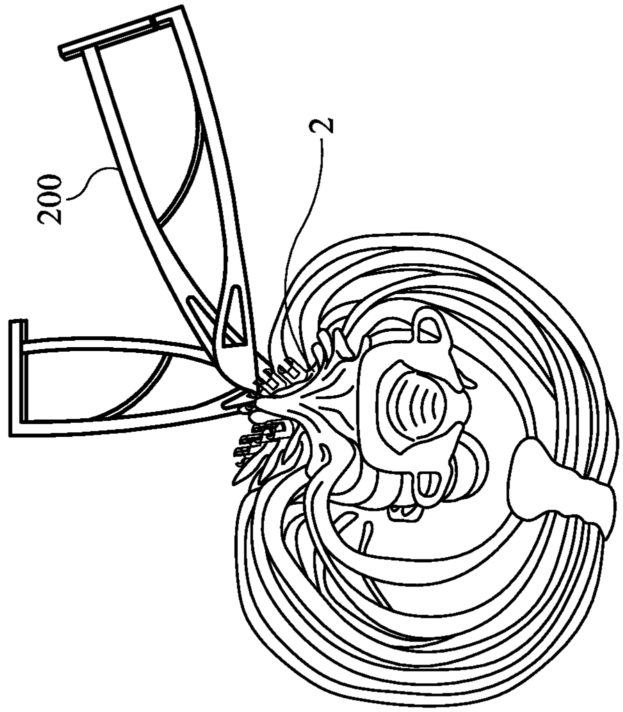

FIG. 14H

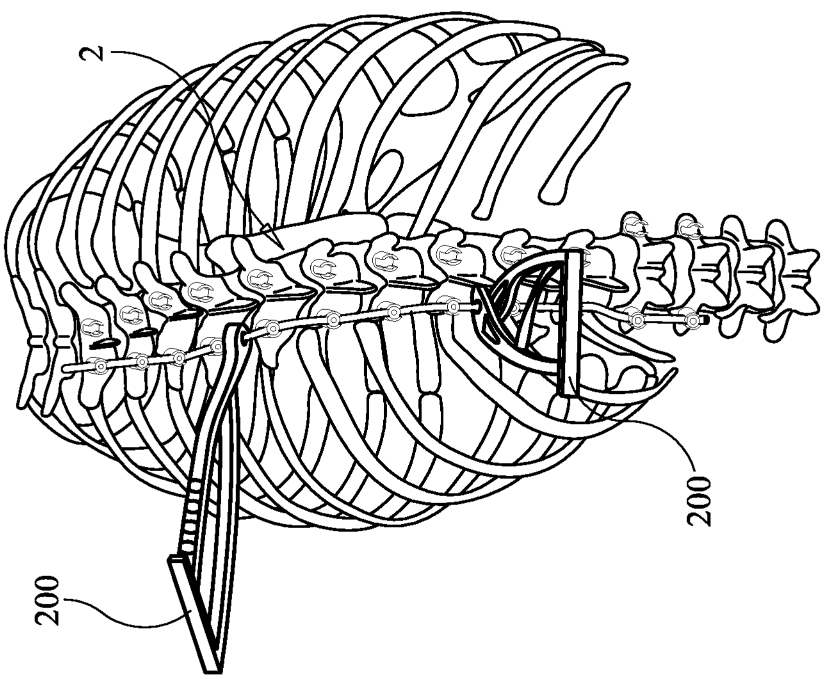

FIG. 14G

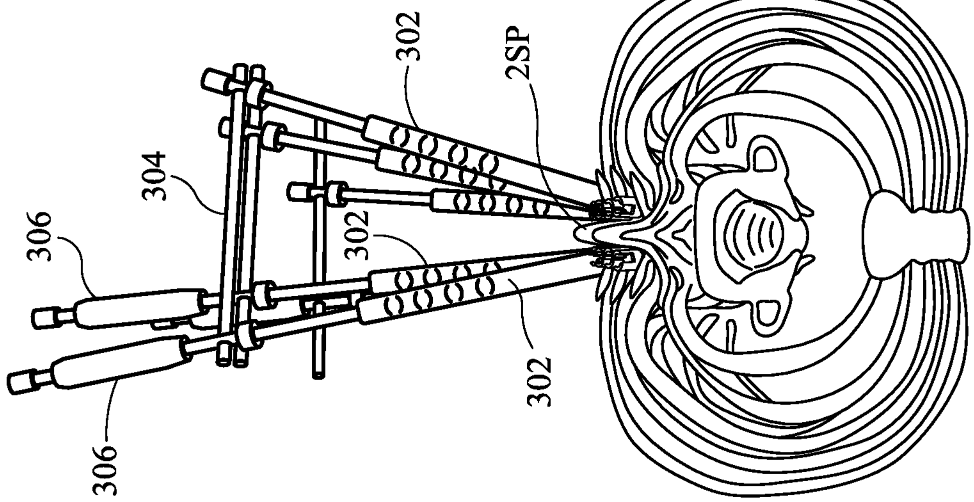

FIG. 14J

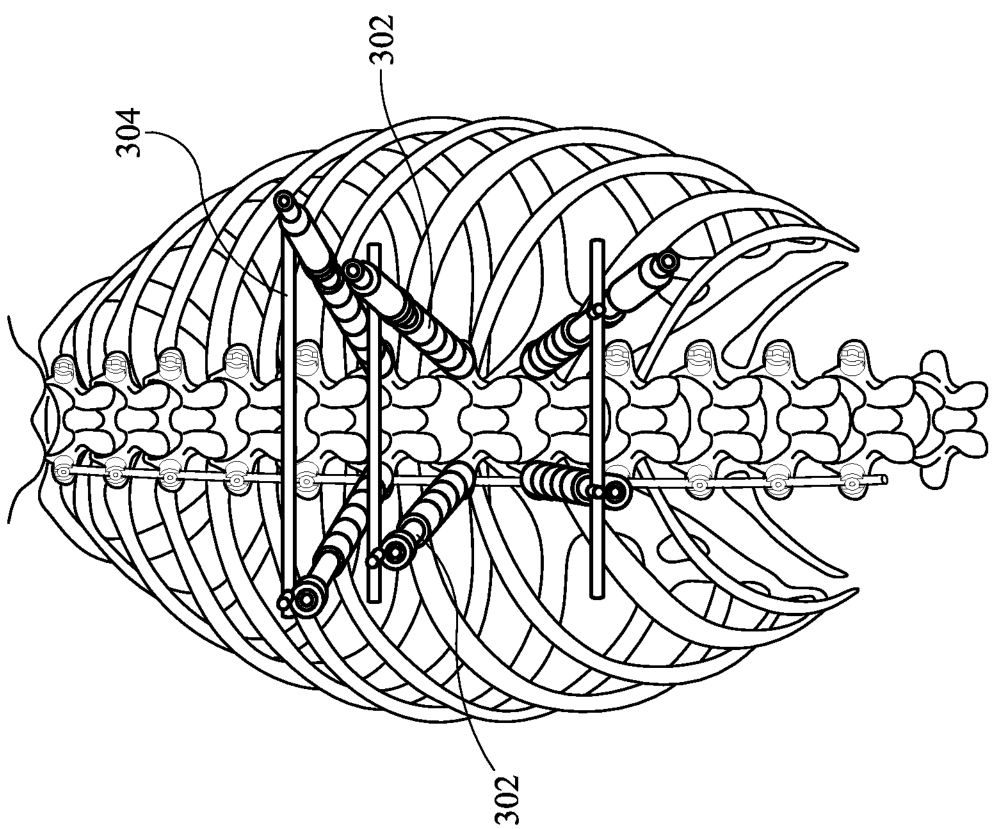

FIG. 14I

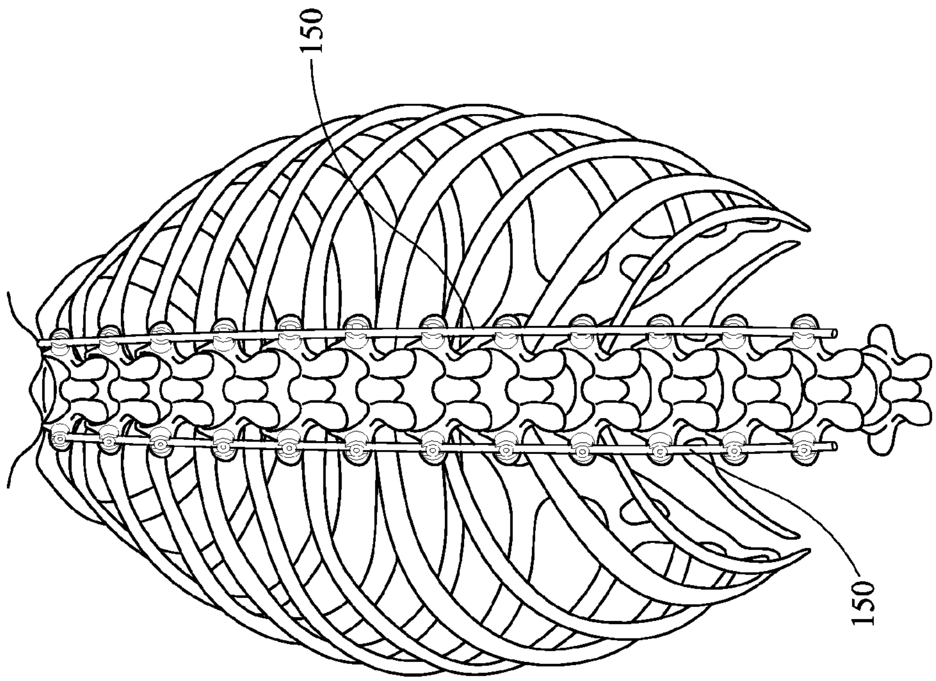

FIG. 14L

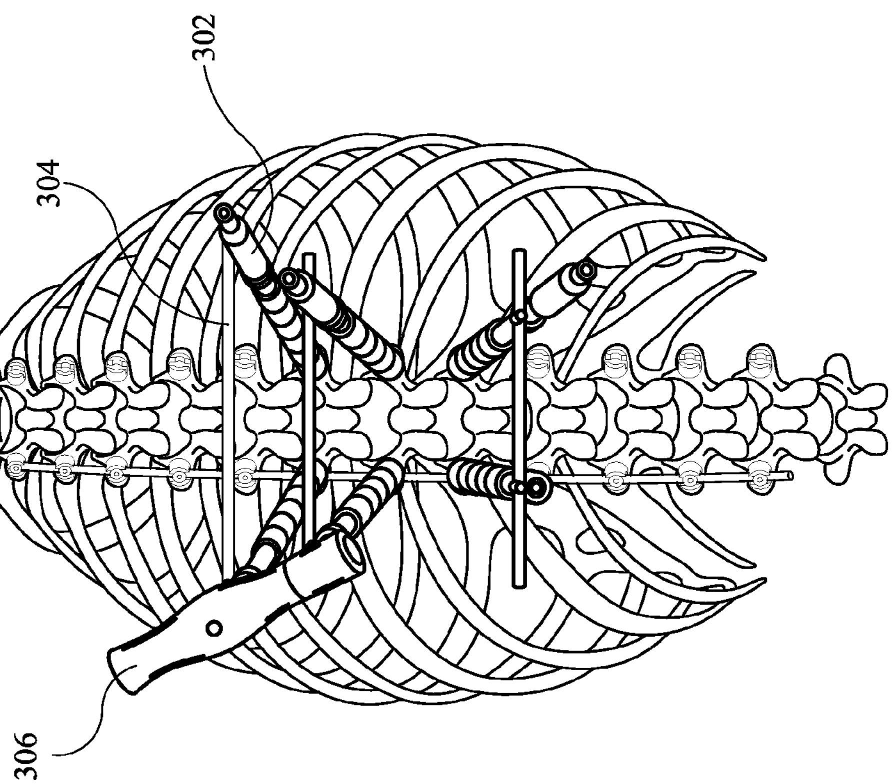

FIG. 14K

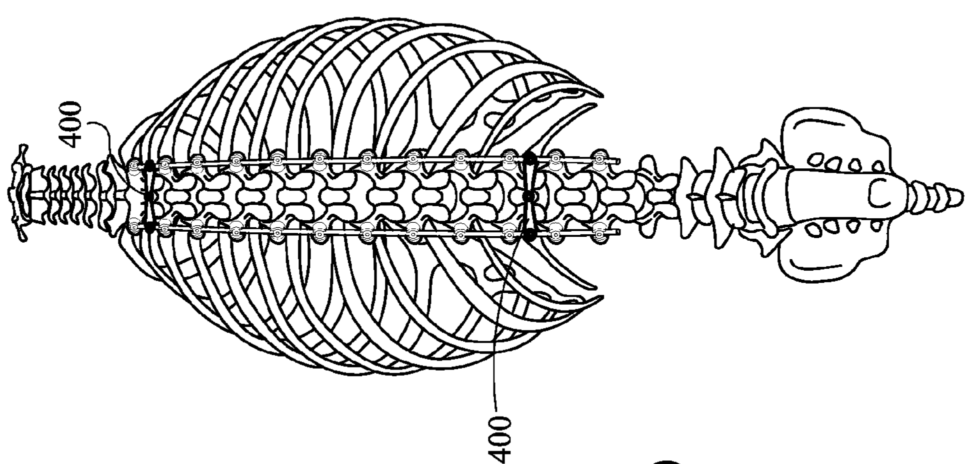

FIG. 14N

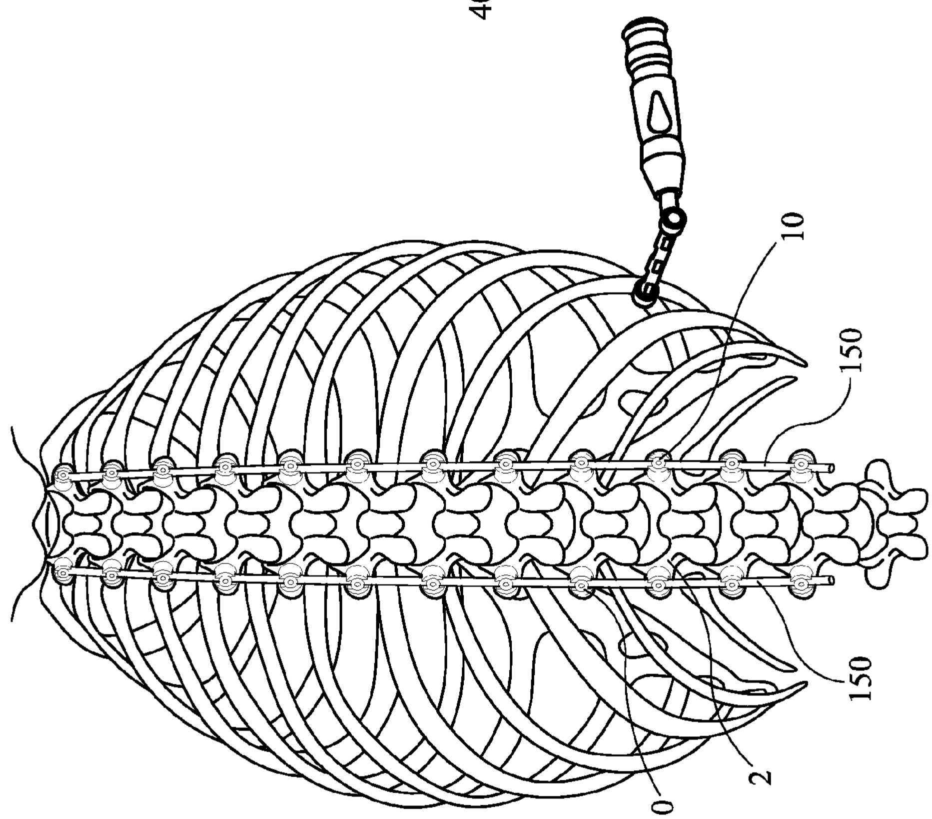

FIG. 14M

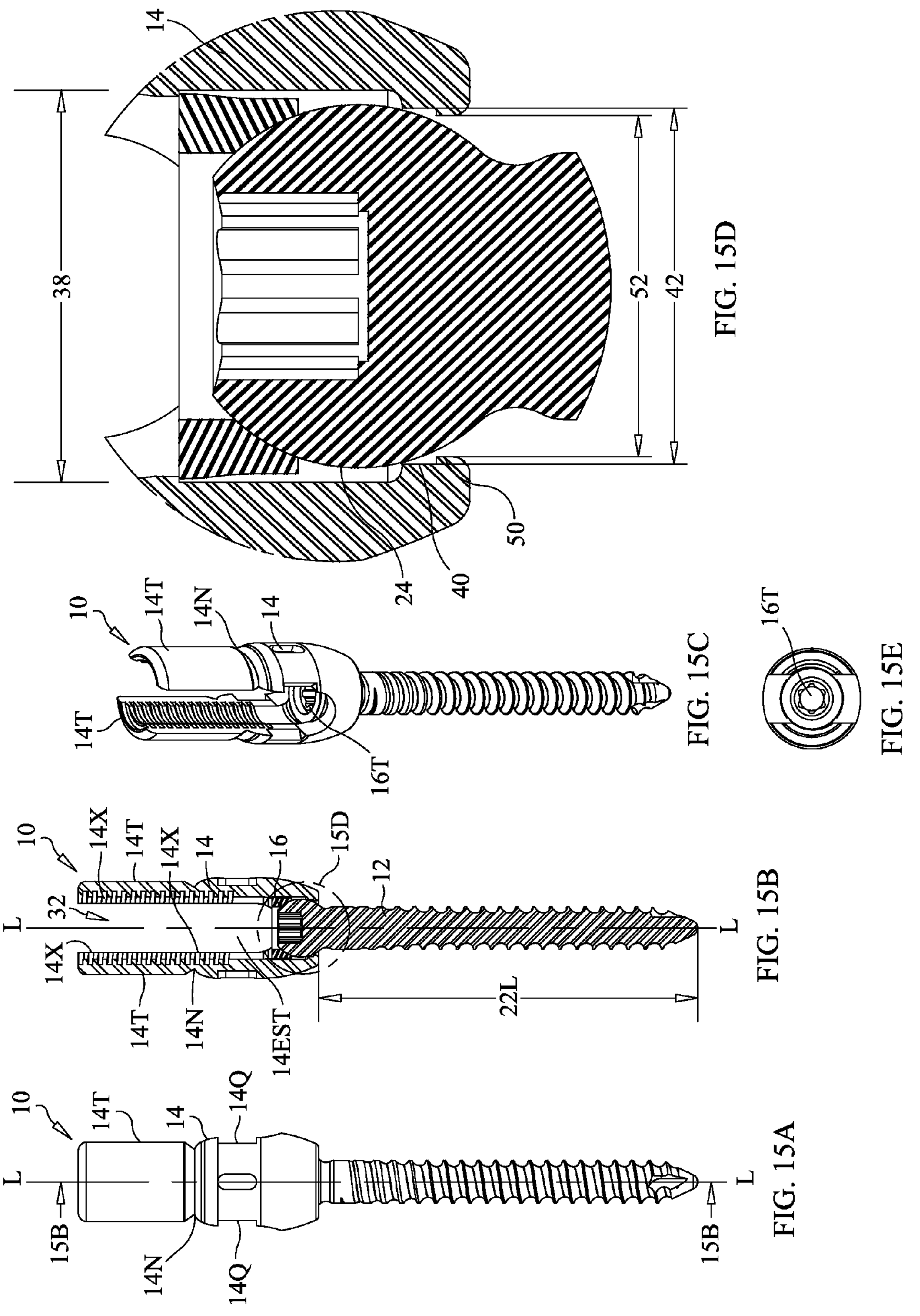

FIG. 15D

FIG. 15C

FIG. 15E

FIG. 15B

FIG. 15A

STAGED LOCKING OF SURGICAL SCREW ASSEMBLY

CROSS-REFERENCE

This application is a continuation-in-part application of co-pending application Ser. No. 13/570,374, filed Aug. 9, 2012 and titled "Uniplanar Surgical Screw Assembly", which is hereby incorporated herein, in its entirety, by reference thereto, and to which application we claim priority under 35 USC §120. This application also references application Ser. No. 13/717,565 filed concurrently herewith and titled "Locking Force Augmentation Features for Polyaxial Screw Assembly", which application is hereby incorporated herein, it its entirety, by reference thereto.

FIELD OF THE INVENTION

The present invention relates to the field of orthopedic surgery, in particular to devices, systems and assemblies for stabilizing and/or fixing bones and/or joints in a patient. More particularly, the present invention relates to polyaxial attachment assemblies including mechanisms for locking the same.

BACKGROUND OF THE INVENTION

The fixation and/or stabilization of bones and/or bone fragments is/are commonly required by orthopedic surgeons to treat injuries such as fractures or disease. To accomplish this, the bones/bone fragments can be joined by a rod, plate or the like, which is fixed to the bones/bone fragments via fasteners such as screws, pins or the like. The connection by the rod(s), plate(s) or the like maintains the bones/bone fragments in a desired orientation and/or at desired spacings, positions, etc. Different situations often require the adjustment of such spacings or orientations, or the removal of the apparatus, sometimes with replacement by another apparatus. For these reasons it is useful to provide fasteners that can be fixed or released, and can also articulate to adjust relative to the rod, plate, or the like, as required by the arrangement of the bones/bone fragments being treated.

In spinal surgery, it is often necessary to secure various implants to the vertebrae and interconnect the vertebrae by attaching one or more rods or plates to the implants. Due to the complex curvature of the spine, as well as irregularities of the same that often need to be treated, it is often difficult to align a rod or plate with all of the implants/fasteners fixed to the various vertebrae to be connected via the rod or plate. By providing fasteners that have some articulation ability, this allows more flexibility in joining the fasteners (and thus the vertebrae that they are attached to) to a rod or plate in the orientations needed.

In some surgeries, it is necessary to span multiple vertebrae of the spine with rods that provide stabilizing forces to the vertebrae to help maintain the desired orientations of the vertebrae o maintain a desired curvature in the spine. In these instances, uniplanar fasteners that allow pivoting in only one plane can be useful, as opposed to the more commonly used polyaxial screws, as polyaxial screws may be more likely to fail by rotating rather than withstanding a lateral force applied to the rod therethrough.

In any case, once the polyaxial or uniplanar fastener has been articulated to the desired angular position of the screw shaft relative to the tulip, there needs to be a mechanism for maintaining that angular position/orientation in a fixed manner, as the orientation should be maintained upon completing the procedure. There is a continuing need for improved fixation mechanisms to maintain fasteners in their desired orientation during use after completion of the procedure. There is a continuing need for improved fixation mechanism that enhance the fixation of fasteners in their desired orientations. It would also be advantageous to provide fasteners with provisional locking capabilities, so that an orientation can be changed, if desired, while still maintaining the ability to relock the fastener with effective locking maintenance force.

SUMMARY OF THE INVENTION

In one aspect of the present invention, a fastener is provided including an elongate shaft having a proximal end and a distal end and a head at the proximal end, the head having an external surface; a tulip having a tulip proximal end portion, a tulip distal end portion, an external surface and an internal bearing surface, said tulip distal end having a bore therethrough defining the internal bearing surface and having a diameter dimensioned to allow the distal end of the elongate shaft to pass therethrough; and locking enhancement features configured to cooperate with the head; wherein, in an unlocked configuration, the head is movable relative to the tulip and the locking enhancement features; in a provisionally locked configuration, the locking enhancement features engage the head with a first polyaxial grip strength; and in a finally locked configuration, the locking enhancement features engage the head with a second polyaxial grip strength, the second polyaxial grip strength being greater than the first polyaxial grip strength.

In at least one embodiment, the locking enhancement features comprise a set of the locking enhancement features; wherein a first subset of the locking enhancement features contact the head in the unlocked configuration; wherein the first subset and a second subset of the locking enhancement features contact the head in the provisionally locked configuration; and wherein the first subset, the second subset and a third subset of the locking enhancement features contact the head in the finally locked configuration.

In at least one embodiment, the fastener is placed in the provisionally locked configuration by applying a provisional locking compression force between the head and the tulip.

In at least one embodiment, the fastener is maintained in the provisionally locked configuration after removal of the provisional locking compression force.

In at least one embodiment, when implanted in a vertebra of a spine of a patient, when in the provisionally locked configuration, and when the provisional locking compression force has been removed, the provisionally locked configuration has sufficient locking strength to prevent relative movement between the tulip and the head when the tulip is driven to cause rotation of the vertebra.

In at least one embodiment, the fastener is placed in the finally locked configuration by applying a final locking compression force between the head and the tulip, wherein the final compression force is greater than a provisional locking compression force required to place the fastener in the provisionally locked configuration.

In at least one embodiment, the locking enhancement features are integral with the tulip.

In at least one embodiment, the locking enhancement features extend inwardly from the internal bearing surface.

In at least one embodiment, the locking enhancement features comprise: a first step feature located at a distal end portion of the bore and extending inwardly from the bore, the first step feature reducing the diameter of the bore to allow the distal end of the elongate shaft to pass therethrough, but prevent passage of the head therethrough as a portion of the first step feature contacts the head; and a second step feature located at a distal end portion of the bore, distally of the first step feature, the second step feature further reducing the diameter of the bore to a dimension less than a dimension established by the first step feature, the further reduced diameter allowing the distal end of the elongate shaft to pass therethrough, but preventing passage of the head therethrough as a portion of the second step feature contacts the head and a portion of the first step feature contacts the head.

In at least one embodiment, the locking enhancement features further comprise a third step feature located at a distal end portion of the bore, distally of the second step feature, the third step feature still further reducing the diameter of the bore to a dimension less than a dimension established by the second step feature, the still further reduced diameter allowing the distal end of the elongate shaft to pass therethrough, but preventing passage of the head therethrough as a portion of the third step feature contacts the head, a portion of the second step feature contacts the head and a portion of the first step feature contacts the head.

In at least one embodiment, the assembly further includes a driving member configured to engage a proximal end portion of the tulip and to establish a compression force between the locking enhancement features and the head.

In at least one embodiment, the tulip further comprises a slot through the proximal end portion extending transverse to the bore, the slot configured to receive a support member; wherein when the support member is received in the slot, when in the provisionally locked configuration, the tulip is prevented from movement relative to the head, but is rotatable relative to the support member; and, wherein in the finally locked configuration, the tulip is prevented from movement relative to the head and is prevented from movement relative to the support member.

In at least one embodiment, the assembly further includes reduction tabs extending proximally of the tulip and extending the slot.

In at least one embodiment, the assembly further includes a saddle, the saddle being configured and dimensioned to be fitted in the tulip proximally of and against the head.

In another aspect of the present invention, a method of operating a surgical screw assembly is provided, including: providing a surgical screw assembly comprising: a fastener including an elongate shaft having a proximal end and a distal end and a head at the proximal end, the head having an external surface; a tulip having a tulip proximal end portion, a tulip distal end portion, an external surface and an internal bearing surface, the tulip distal end having a bore therethrough defining the internal bearing surface and having a diameter dimensioned to allow the distal end of the elongate shaft to pass therethrough; and locking enhancement features configured to cooperate with the head; wherein, in an unlocked configuration, the tulip is free to rotate relative to the head; attaching a support member to the assembly; applying a first compression force between the tulip and the locking enhancement features, wherein the locking enhancement features engage with the head to place the assembly in a provisionally locked configuration; wherein, in the provisionally locked configuration, the tulip is prevented from rotating relative to the head, but the tulip is movable relative to the support member.

In at least one embodiment, the fastener further comprises reduction tabs extending proximally form the tulip, and wherein the attaching a support member comprises positioning the support member between the reduction tabs, relatively moving the fastener and the support member toward one another so that the support member is positioned within the tulip, and removing the reduction tabs from the tulip after the attaching a support member to the assembly.

In at least one embodiment, the method includes relatively rotating one of the support member and the tulip relative to the other, while the provisionally locked configuration prevents the tulip from rotating relative to the head.

In at least one embodiment, the method includes removing the first compression force, whereby the assembly is maintained in the provisionally locked configuration after the removing the first compression force.

In at least one embodiment, the method includes applying a second compression force greater than the first compression force between the tulip and the locking enhancement features, wherein the locking enhancement features engage with the head in a finally locked configuration; wherein, in the finally locked configuration, the tulip is prevented from rotating relative to the head, and the tulip is prevented from moving relative to the support member.

In another aspect of the present invention, a method of using a surgical screw assembly in a surgical procedure is provided, including: providing a surgical screw assembly comprising: a fastener including an elongate shaft having a proximal end and a distal end and a head at the proximal end, the head having an external surface; a tulip having a tulip proximal end portion, a tulip distal end portion, an external surface and an internal bearing surface, the tulip distal end having a bore therethrough defining the internal bearing surface and having a diameter dimensioned to allow the distal end of the elongate shaft to pass therethrough; and locking enhancement features configured to cooperate with the head; wherein, in an unlocked configuration, the tulip is free to rotate relative to the head; implanting the shaft into a vertebra of a patient; attaching a support member to the assembly; applying a first compression force between the tulip and the locking enhancement features, wherein the locking enhancement features engage with the head to place the assembly in a provisionally locked configuration; and applying a force to the tulip to rotate the vertebra relative to the support member, and rotating the tulip and the vertebra relative to the support member while the tulip is prevented from rotating relative to the shaft.

In at least one embodiment, when the vertebra has been rotated to a desired orientation, the method includes applying a second compression force greater than the first compression force between the tulip and the locking enhancement features, while maintaining the desired orientation, wherein the locking enhancement features engage with the head to place the assembly in a finally locked configuration, the vertebra is prevented from rotating relative to the support member and the tulip is prevented from rotating relative to the support member.

In at least one embodiment, the method includes applying a second force to the tulip to drive the vertebra toward or away from an adjacent vertebra.

These and other features of the invention will become apparent to those persons skilled in the art upon reading the details of the assemblies and methods as more fully described below.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A is a plan view of a uniplanar surgical screw assembly according to an embodiment of the present invention.

FIG. **1**B shows the assembly of FIG. **1**A having been rotated about its longitudinal axis L-L by ninety degrees, relative to the view shown in FIG. **1**A.

FIG. 1C is a longitudinal sectional view of the embodiment of FIG. 1A taken along line 1C-1C.

FIG. 1D shows the assembly of FIG. 1C, after pivoting the shaft relative to the tulip.

FIG. 1E is an enlarged detailed view of the portion of FIG. 1C within circle 1E.

FIG. 1F is a cross sectional view of the assembly taken along line 1F-1F in FIG. 1C.

FIG. 1G is an isolated, perspective view of the tulip component of FIG. 1A.

FIG. 1H is an isolated, perspective view of the saddle component of FIG. 1A.

FIG. 1I is an isolated, perspective view of an insert component of FIG. 1A.

FIG. 1J is an isolated, perspective view of the fastener component of FIG. 1A.

FIG. 2A is a plan view of a uniplanar surgical screw assembly according to another embodiment of the present invention.

FIG. 2B shows the assembly of FIG. 2A having been rotated about its longitudinal axis L-L by ninety degrees, relative to the view shown in FIG. 2A.

FIG. 2C is a longitudinal sectional view of the embodiment of FIG. 2A taken along line 2C-2C.

FIG. 2D shows the assembly of FIG. 2C, after pivoting the shaft relative to the tulip.

FIG. 2E is an enlarged detailed view of the portion of FIG. 2C within circle 2E.

FIG. 2F is a cross sectional view of the assembly taken along line 2F-2F in FIG. 2C.

FIG. 2G is an isolated, perspective view of the fastener of FIG. 2A.

FIG. 2H is an isolated, perspective view of the tulip component of FIG. 2A.

FIG. 2I is an isolated, perspective view of the saddle component of FIG. 2A.

FIG. 2J is an isolated, perspective view of the insert component of FIG. 2A.

FIG. 3A is a plan view of a uniplanar surgical screw assembly according to another embodiment of the present invention.

FIG. 3B shows the assembly of FIG. 3A having been rotated about its longitudinal axis L-L by ninety degrees, relative to the view shown in FIG. 3A.

FIG. 3C is a longitudinal sectional view of the embodiment of FIG. 3A taken along line 3C-3C.

FIG. 3D shows the assembly of FIG. 3C, after pivoting the shaft relative to the tulip.

FIG. 3E is an enlarged detailed view of the portion of FIG. 3C within circle 3E.

FIG. 3F is a cross sectional view of the assembly taken along line 3F-3F in FIG. 3C.

FIG. 3G is an isolated, perspective view of the fastener of FIG. 3A.

FIG. 3H is an isolated, perspective view of the tulip component of FIG. 3A.

FIG. 3I is an isolated, perspective view of the saddle component of FIG. 3A.

FIG. 4A is a plan view of a uniplanar surgical screw assembly according to another embodiment of the present invention.

FIG. 4B shows the assembly of FIG. 4A having been rotated about its longitudinal axis L-L by ninety degrees, relative to the view shown in FIG. 4A.

FIG. 4C is a longitudinal sectional view of the embodiment of FIG. 4A taken along line 4C-4C.

FIG. 4D shows the assembly of FIG. 4C, after pivoting the shaft relative to the tulip.

FIG. 4E is an enlarged detailed view of the portion of FIG. 4C within circle 4E.

FIG. 4F is a cross sectional view of the assembly taken along line 4F-4F in FIG. 4C.

FIG. 4G is an isolated, perspective view of the fastener of FIG. 4A.

FIG. 4H is an isolated, perspective view of the tulip component of FIG. 4A.

FIG. 4I is an isolated, perspective view of the saddle component of FIG. 4A.

FIG. 5A is a plan view of a uniplanar surgical screw assembly according to another embodiment of the present invention.

FIG. 5B is a longitudinal sectional view of the embodiment of FIG. 5E taken along line 5B-5B.

FIG. 5C is a cross sectional view of the assembly taken along line 5C-5C in FIG. 5B.

FIG. 5D is an enlarged detailed view of the portion of FIG. 5B within circle 5D.

FIG. 5E shows the assembly of FIG. 5A having been rotated about its longitudinal axis L-L by ninety degrees, relative to the view shown in FIG. 5A.

FIG. 5F shows the assembly of FIG. 5B, after pivoting the shaft relative to the tulip.

FIG. 5G is an isolated, perspective view of the fastener of FIG. 5A.

FIG. 5H is an isolated, perspective view of the tulip component of FIG. 5A.

FIG. 5I is an isolated, perspective view of the saddle component of FIG. 5A.

FIG. 5J is an isolated, perspective view of a flat insert component of FIG. 5A.

FIG. 6A is a plan view of a uniplanar surgical screw assembly according to another embodiment of the present invention.

FIG. 6B is a longitudinal sectional view of the embodiment of FIG. 6E taken along line 6B-6B.

FIG. 6C is a cross sectional view of the assembly taken along line 6C-6C in FIG. 6B.

FIG. 6D is an enlarged detailed view of the portion of FIG. 6B within circle 6D.

FIG. 6E shows the assembly of FIG. 6A having been rotated about its longitudinal axis L-L by ninety degrees, relative to the view shown in FIG. 6A.

FIG. 6F shows the assembly of FIG. 6B, after pivoting the shaft relative to the tulip.

FIG. 6G is an isolated, perspective view of the fastener of FIG. 6A.

FIG. 6H is an isolated, perspective view of the tulip component of FIG. 6A.

FIG. 6I is an isolated, perspective view of the saddle component of FIG. 6A.

FIG. 6J is an isolated, perspective view of the flat insert component of FIG. 6A.

FIG. 7A is a plan view of a uniplanar surgical screw assembly according to another embodiment of the present invention.

FIG. 7B shows the assembly of FIG. 7A having been rotated about its longitudinal axis L-L by ninety degrees, relative to the view shown in FIG. 7A.

FIG. 7C is a longitudinal sectional view of the embodiment of FIG. 7A taken along line 7C-7C.

FIG. 7D shows the assembly of FIG. 7C, after pivoting the shaft relative to the tulip.

FIG. 7E is an enlarged detailed view of the portion of FIG. 7C within circle 7E.

FIG. 7F is a cross sectional view of the assembly taken along line 7F-7F in FIG. 7C.

FIG. 7G is an isolated, perspective view of the fastener of FIG. 7A.

FIG. 7H is an isolated, perspective view of the tulip component of FIG. 7A.

FIG. 7I is an isolated, perspective view of the saddle component of FIG. 7A.

FIG. 8A is a plan view of a uniplanar surgical screw assembly according to another embodiment of the present invention.

FIG. 8B shows the assembly of FIG. 8A having been rotated about its longitudinal axis L-L by ninety degrees, relative to the view shown in FIG. 8A.

FIG. 8C is a longitudinal sectional view of the embodiment of FIG. 8A taken along line 8C-8C.

FIG. 8D shows the assembly of FIG. 8C, after pivoting the shaft relative to the tulip.

FIG. 8E is an enlarged detailed view of the portion of FIG. 8C within circle 8E.

FIG. 8F is a cross sectional view of the assembly taken along line 8F-8F in FIG. 8C.

FIG. 8G is an isolated, perspective view of the fastener of FIG. 8A.

FIG. 8H is an isolated, perspective view of the tulip component of FIG. 8A.

FIG. 8I is an isolated, perspective view of the saddle component of FIG. 8A.

FIG. 9A is a plan view of a uniplanar surgical screw assembly according to another embodiment of the present invention.

FIG. 9B shows the assembly of FIG. 9A having been rotated about its longitudinal axis L-L by ninety degrees, relative to the view shown in FIG. 9A.

FIG. 9C is a longitudinal sectional view of the embodiment of FIG. 9A taken along line 9C-9C.

FIG. 9D shows the assembly of FIG. 9C, after pivoting the shaft relative to the tulip.

FIG. 9E is an enlarged detailed view of the portion of FIG. 9C within circle 9E.

FIG. 9F is a cross sectional view of the assembly taken along line 9F-9F in FIG. 9C.

FIG. 9G is an isolated, perspective view of the fastener of FIG. 9A.

FIG. 9H is an isolated, perspective view of the tulip component of FIG. 9A.

FIG. 9I is an isolated, perspective view of the saddle component of FIG. 9A.

FIG. 10 is a longitudinal sectional view of an assembly locked to a rod according to an embodiment of the present invention.

FIG. 11A is a plan view of a uniplanar surgical screw assembly according to another embodiment of the present invention.

FIG. 11B is a view of the embodiment of FIG. 11A after rotation about the longitudinal axis by ninety degrees.

FIG. 11C is a longitudinal sectional view of the embodiment of FIG. 11B taken along line 11C-11C.

FIG. 11D is a view showing the fastener angled relative to the tulip, according to an embodiment of the present invention.

FIG. 11E is an enlarged detailed view of the portion of FIG. 11C within circle 11E.

FIG. 11F is a cross-sectional view of the assembly taken along line 11F-11F in FIG. 11C

FIG. 11G is an isolated, perspective view of the tulip component of FIGS. 11A-11F.

FIG. 11H is an isolated, perspective view of the saddle component of FIGS. 11A-11F.

FIG. 11I is an isolated, perspective view of the fastener component of FIGS. 11A-11F.

FIG. 11J is a proximal end view of FIG. 11B.

FIG. 12A is a plan view of a surgical screw assembly according to another embodiment of the present invention.

FIG. 12B is a longitudinal sectional view of the assembly of FIG. 12A taken along line 12B-12B.

FIG. 12C is a perspective view of the assembly shown in FIG. 12A.

FIG. 12D is an enlarged detailed view of the portion of FIG. 12B within circle 12D.

FIG. 12E is a proximal end view of the assembly of FIG. 12A.

FIG. 12F is a longitudinal sectional view of the assembly of FIG. 12A, similar to that shown in FIG. 12B, but when the assembly is in a locked configuration.

FIG. 12G is an enlarged detailed view of the portion of FIG. 12F within circle 12G.

FIGS. 12H-12L illustrate various arrangements of first and second step features according to embodiments of the present invention.

FIG. 13A is a plan view of a surgical screw assembly in an unlocked configuration according to another embodiment of the present invention.

FIG. 13B is a longitudinal sectional view of the assembly of FIG. 13A taken along line 13B-13B.

FIG. 13C is a perspective view of the assembly shown in FIG. 13A.

FIG. 13D is an enlarged detailed view of the portion of FIG. 13B within circle 13D.

FIG. 13E is a proximal end view of the assembly of FIG. 13A.

FIG. 13F is an enlarged detailed view of the portion of FIG. 13D within ellipse 13F.

FIG. 13G is a plan view of the surgical screw assembly of FIG. 13A in a provisionally locked configuration according to an embodiment of the present invention.

FIG. 13H is a longitudinal sectional view of the assembly of FIG. 13B taken along line 13H-13H.

FIG. 13I is a perspective view of the assembly shown in FIG. 13G.

FIG. 13J is an enlarged detailed view of the portion of FIG. 13H within circle 13J.

FIG. 13K is a proximal end view of the assembly of FIG. 13G.

FIG. 13L is an enlarged detailed view of the portion of FIG. 13J within ellipse 13L.

FIG. 13M is a plan view of the surgical screw assembly of FIGS. 13A and 13G in a fully locked configuration according to an embodiment of the present invention.

FIG. 13N is a longitudinal sectional view of the assembly of FIG. 13M taken along line 13N-13N.

FIG. 13O is a perspective view of the assembly shown in FIG. 13M.

FIG. 13P is an enlarged detailed view of the portion of FIG. 13N within circle 13P.

FIG. 13Q is a proximal end view of the assembly of FIG. 13M.

FIG. 13R is an enlarged detailed view of the portion of FIG. 13P within ellipse 13R.

FIGS. 14A-14N illustrate steps that may be performed in carrying out a surgical procedure according to an embodiment of the present invention.

FIGS. **15**A-**15**E illustrate a fastener **10** with extended reduction tabs **14**T according to an embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Before the present assemblies, components and systems are described, it is to be understood that this invention is not limited to particular embodiments described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present invention will be limited only by the appended claims.

Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limits of that range is also specifically disclosed. Each smaller range between any stated value or intervening value in a stated range and any other stated or intervening value in that stated range is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included or excluded in the range, and each range where either, neither or both limits are included in the smaller ranges is also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the invention.

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, the preferred methods and materials are now described. All publications mentioned herein are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited.

It must be noted that as used herein and in the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to “a location” includes a plurality of such locations and reference to “the screw” includes reference to one or more screws and equivalents thereof known to those skilled in the art, and so forth.

The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

The embodiments described below are directed to uniplanar and polyaxial screw assemblies for use with an orthopedic rod. Although the following description is related to such use with an orthopedic rod, for example for surgical procedures treating the spine, it is noted that the present invention as described can be used in other applicable surgical procedures, such as in other orthopedic procedures for fixing and/or aligning bones, joints, etc. Furthermore, although the specific embodiments shown in the figures and described below employ a screw as a fastener, it should be understood that other types of fasteners or securing elements may alternatively or additionally be used, including, but not limited to lamina hooks, sacral blocks, etc. Furthermore, the assemblies described can be used with a plate, shaft, channel, or the like, alternatively or in addition to use with a rod.

Definitions

The term “provisional locking” refers to a locking configuration of a fastener according to the present invention that provide sufficient polyaxial grip of a tulip relative to the head of the fastener to withstand forces applied to the tulip during a vertebral body derotation procedure, without allowing movement of the tulip relative to the head.

The term “final locking” refers to a locking configuration that a fastener is placed in to be maintained during the life of the implant. The force applied to place the fastener into the final locking configuration is greater than the force required to place the fastener into the provisional locking configuration, with all other variables kept the same.

Description

Referring now to FIG. **1**A, a plan view of a uniplanar surgical screw assembly **10** is shown, according to an embodiment of the present invention. FIG. **1**B shows assembly **10** having been rotated about its longitudinal axis L-L by ninety degrees, relative to the view shown in FIG. **1**A. The assembly **10** of the embodiment of FIGS. **1**A-**1**J includes a fastener **12** (see the isolated view of FIG. **1**J), a saddle-shaped tulip **14** (see the isolated view of FIG. **1**G), a saddle **16** (see the isolated view of FIG. **1**H) and a pair of inserts **18** (see isolated view of an insert **18** in FIG. **1**I).

Fastener **12** includes an elongate shaft **22** having a proximal end and a distal end and a head **24** at the proximal end thereof. As shown, elongate shaft **22** is a screw shaft having threads **26** therealong. Head **24** includes a pair of slots **28** that extend in a proximal-distal direction aligned with the longitudinal axis L-L.

The tulip **14** has a bore **32** therethrough that is dimensioned to allow the distal end of elongate shaft **12** to pass therethrough, but the dimension of the distal opening **32**D is smaller than the largest cross-sectional dimension of the head **24**, and thereby prevents passage of the head **24** therethrough, as illustrated in FIGS. **1**A-**1**E. Inserts **18** are fixed at **34** to tulip **14** as shown in FIG. **1**C, so as to protrude into the bore **32**. Slots **28** are configured and dimensioned to receive the protruding ends of inserts **18**, to allow inserts **18** to freely slide therein in the proximal distal direction, but to prevent movements in any other directions. Inserts **18** may be fixed to tulip **14** by adhesives, welding, press fitting and/or other fixation expedients, preferably by press fitting into receptacles **34** formed in tulip **14**. As shown in FIGS. **1**C-**1**E, slots **28** are formed diametrically opposite one another, separated by 180 degrees around the head **24**. This is necessary to allow both inserts **18** to slide in the same plane, resulting in an assembly that allows the elongate shaft **22** to pivot relative to the tulip **14** in one plane only. FIG. **1**C shows a longitudinal sectional view of assembly **10** taken along line **1**C-**1**C of FIG. **1**A. FIGS. **1**A-**1**C illustrate the assembly **10** where the fastener **12** is aligned with the longitudinal axis L-L of the assembly **10** and tulip **14**. FIG. **1**D shows the longitudinal sectional view of FIG. **1**C, but after uniplanar pivoting of fastener **12**/shaft **22** relative to tulip **14** by an angle **36** (as shown by the angle **36** between the longitudinal axis L'-L' of the fastener **12** and the longitudinal axis L-L of the tulip **14**. The uniplanar range of motion may include angulation of up to about ±40°, typically a range of up to about ±22°, wherein the plus and minus values indicate the angle **36** in the direction shown in FIG. **1**D and the same amount of angulation in the opposite direction in that plane.

Saddle **16** is configured and dimensioned to be fixed relative to tulip **14** while abutting the proximal portion of head **24** as shown in FIG. **1**C. Saddle **16** has a concave distal surface

16*s* configured and dimensioned as a bearing surface to allow the convex curvature of head **24** to slide relative thereto. Accordingly, as shaft **22** is pivoted relative to tulip **14**, head **24** rotates against bearing surfaces of the tulip **14** and saddle **16**, as illustrated in FIG. **1**D. FIG. **1**D illustrates a maximum angle **36** of pivoting, as inserts **18** make contact with the ends of slots **28**, respectively. As shown in FIG. **1**E, inserts **18** are centered in slots **28** when shaft **22** is aligned with the longitudinal axis L-L of the tulip **14**. Alternatively, slots **28** could be asymmetrically formed so as to allow angulation **36** on one side of the longitudinal axis L-L to be greater than angulation on the other side (angulation the opposite direction).

In the embodiment shown, saddle **16** is a standard saddle and is configured and dimensioned to be retained by shoulder **14**S when fitted into tulip **14**, see FIG. **1**G. The saddle-shaped tulip **14** further includes a slot **14**ST passing therethrough, as shown in FIGS. **1**A and **1**G that is configured and dimensioned to receive an orthopedic rod or plate therein, in manners known in the art. Threading **14**X allows a set screw **46** or the like to be torqued against the rod, plate, channel or shaft **150** to fix it relative to the tulip **14** (see FIG. **10**). The saddle **16** is configured to apply compression to the head **24** to lock an orientation of the fastener **12** relative to the tulip **14**, thereby even preventing the movement in the one plane that is otherwise allowed, and thus preventing movement in all planes. The set screw **46** presses on the rod, plate, channel or shaft **150** and the head **24** of the shaft is squeezed in between the saddle and the bottom of the tulip **14**.

All components **12**,**14**,**16** and **18** of assembly **10** are preferably made of titanium. Alternatively, one or more components may be made of stainless steel, or other known, rigid materials used as substitute materials in the art, which may include other biocompatible metals, plastics and/or composites. The uniplanar angulation of assembly **10** may vary, but preferably has a range of about eighty degrees (twice angle **36**). The dimensions of the components will vary depending upon the location of the spine in which they are used, the size of the patient (e.g., pediatric vs. adult, male vs. female, etc.), etc. The outside diameter of tulip **14** typically falls within a range of about 8 mm to about 16 mm. The outside diameter of shaft **22** typically falls within a range of about 3 mm to about 10 mm. The length of shaft **22** typically falls within a range of about 10 mm to about 100 mm. The height **18**H of insert **18** is about 1 mm to about 2 mm, typically about 1.5 mm. The length **18**L: of insert **18** is about 1.5 mm to about 3 mm, typically about 2.25 mm.

Referring now to FIG. **2**A, a plan view of a uniplanar surgical screw assembly **10** is shown, according to another embodiment of the present invention. FIG. **2**B shows assembly **10** having been rotated about its longitudinal axis L-L by ninety degrees, relative to the view shown in FIG. **2**A. The assembly **10** of the embodiment of FIGS. **2**A-**2**J includes a fastener **12** (see the isolated view of FIG. **2**G), a saddle-shaped tulip **14** (see the isolated view of FIG. **2**H), a saddle **16** (see the isolated view of FIG. **2**I) and only one insert **18** (see isolated view in FIG. **2**J), in contrast to the pair of inserts **18** employed in the embodiment of FIGS. **1**A-**1**J.

Fastener **12** includes an elongate shaft **22** having a proximal end and a distal end and a head **24** at the proximal end thereof. As shown, elongate shaft **22** is a screw shaft having threads **26** therealong. Head **24** includes a slot **28** that extends in a proximal-distal direction aligned with the longitudinal axis L-L.

The tulip **14** has a bore **32** therethrough that is dimensioned to allow the distal end of elongate shaft **12** to pass therethrough, but the dimension of the distal opening **32**D is smaller than the largest cross-sectional dimension of the head **24**, and thereby prevents passage of the head **24** therethrough, as illustrated in FIGS. **2**A-**2**E. Insert **18** is fixed at **34** to tulip **14** as shown in FIG. **2**E, so as to protrude into the bore **32**. Slot **28** is configured and dimensioned to receive the protruding end of insert **18**, to allow insert **18** to freely slide therein in the proximal distal direction, but to prevent movements in any other directions. Insert **18** may be fixed to tulip **14** by adhesives, welding, press fitting and/or other fixation expedients, preferably by press fitting into receptacle **34** formed in tulip **14**. Slot **28** is formed to allow insert **18** to slide only in a proximal-distal direction that permits pivoting of the shaft **22** relative to the tulip **14** in one plane only. FIG. **2**C shows a longitudinal sectional view of assembly **10** taken along line **2**C-**2**C of FIG. **2**A. FIGS. **2**A-**2**C illustrate the assembly **10** where the fastener **12** is aligned with the longitudinal axis L-L of the assembly **10** and tulip **14**. FIG. **2**D shows the longitudinal sectional view of FIG. **2**C, but after uniplanar pivoting of fastener **12**/shaft **22** relative to tulip **14** by an angle **36** (as shown by the angle **36** between the longitudinal axis L'-L' of the fastener **12** and the longitudinal axis L-L of the tulip **14**.

Saddle **16** is configured and dimensioned to be fixed relative to tulip **14** while abutting the proximal portion of head **24** as shown in FIG. **2**C. Saddle **16** has a concave distal surface **16**S configured and dimensioned as a bearing surface to allow the convex curvature of head **24** to slide relative thereto. Accordingly, as shaft **22** is pivoted relative to tulip **14**, head **24** rotates against bearing surfaces of the tulip **14** and saddle **16**, as illustrated in FIG. **2**D. FIG. **2**D illustrates a maximum angle **36** of pivoting in one direction, as insert **18** makes contact with the end of slot **28**. As shown in FIG. **2**E, insert **18** is centered in slot **28** when shaft **22** is aligned with the longitudinal axis L-L of the tulip **14**. Alternatively, slot **28** could be asymmetrically formed so as to allow angulation **36** on one side of the longitudinal axis L-L to be greater than angulation on the other side (angulation the opposite direction).

In the embodiment shown, saddle **16** is a standard saddle and is configured and dimensioned to be retained by shoulder **14**S when fitted into tulip **14**, see FIG. **2**H. The saddle-shaped tulip **14** further includes a slot **14**ST passing therethrough, as shown in FIGS. **2**A and **2**G that is configured and dimensioned to receive an orthopedic rod or plate therein, in manners known in the art. Threading **14**X allows a set screw (not shown) or the like to be torqued against the rod/plate to fix it relative to the tulip **14**. The saddle **16** is configured to apply compression to the head **24** to lock an orientation of the fastener **12** relative to the tulip **14**, thereby even preventing the movement in the one plane that is otherwise allowed, and thus preventing movement in all planes, by locking down with the set screw in a manner described above.

All components **12**,**14**,**16** and **18** of assembly **10** are preferably made of titanium. Alternatively, one or more components may be made of alternative materials, the same as described above with regard to the previous embodiment. The uniplanar angulation of assembly **10** may vary, but preferably has a range of about eighty (80) degrees (twice angle **36**). The dimensions of the components will vary depending upon the location of the spine in which they are used, the size of the patient (e.g., pediatric vs. adult, male vs. female, etc.), etc. The outside diameter of tulip **14** typically falls within a range of about 8 mm to about 16 mm. The outside diameter of shaft **22** typically falls within a range of about 3 mm to about 10 mm. The length of shaft **22** typically falls within a range of about 10 mm to about 100 mm. The height **18**H of insert **18** is about 1 mm to about 2 mm, typically about 1.5 mm. The length **18**L of insert **18** is about 1.5 mm to about 3 mm, typically about 2.25 mm.

FIG. **3**A is a plan view of a uniplanar surgical screw assembly **10** according to another embodiment of the present invention. FIG. **3**B shows assembly **10** having been rotated about its longitudinal axis L-L by ninety degrees, relative to the view shown in FIG. **3**A. The assembly **10** of the embodiment of FIGS. **3**A-**3**I includes a fastener **12** (see the isolated view of FIG. **3**G), a saddle-shaped tulip **14** (see the isolated view of FIG. **3**H), and a saddle **16** (see the isolated view of FIG. **3**I). Rather than employing one or more inserts **18**, the embodiment of FIGS. **3**A-**3**I provides protrusions **48** integrally formed with tulip **14** and protruding into the open space formed by the bore **32**, as shown in FIGS. **3**C-**3**F.

Fastener **12** includes an elongate shaft **22** having a proximal end and a distal end and a head **24** at the proximal end thereof. As shown, elongate shaft **22** is a screw shaft having threads **26** therealong. Head **24** includes a pair of slots **28** that extend in a proximal-distal direction aligned with the longitudinal axis L-L.

The tulip **14** has a bore **32** therethrough that is dimensioned to allow the distal end of elongate shaft **22** to pass therethrough, but the dimension of the distal opening **32**D is smaller than the largest cross-sectional dimension of the head **24**, and thereby prevents passage of the head **24** therethrough, as illustrated in FIGS. **3**A-**3**E. Slots **28** are configured and dimensioned to receive the protruding ends of protrusions **48**, to allow protrusions **48** to freely slide therein in the proximal distal direction, but to prevent movements in any other directions. As shown in FIGS. **3**C-**3**F, slots **28** are formed diametrically opposite one another, separated by 180 degrees around the head **24**. This is necessary to allow both protrusions **48** to slide in the same plane, resulting in an assembly that allows the elongate shaft **22** to pivot relative to the tulip **14** in one plane only. FIG. **3**C shows a longitudinal sectional view of assembly **10** taken along line **3**C-**3**C of FIG. **1**A. FIGS. **3**A-**3**C illustrate the assembly **10** where the fastener **12** is aligned with the longitudinal axis L-L of the assembly **10** and tulip **14**. FIG. **3**D shows the longitudinal sectional view of FIG. **3**C, but after uniplanar pivoting of fastener **12**/shaft **22** relative to tulip **14** by an angle **36** (as shown by the angle **36** between the longitudinal axis L'-L' of the fastener **12** and the longitudinal axis L-L of the tulip **14**.

Saddle **16** is configured and dimensioned to be fixed relative to tulip **14** while abutting the proximal portion of head **24** as shown in FIG. **3**C. Saddle **16** has a concave distal surface **16**S configured and dimensioned as a bearing surface to allow the convex curvature of head **24** to slide relative thereto. Accordingly, as shaft **22** is pivoted relative to tulip **14**, head **24** rotates against bearing surfaces of the tulip **14** and saddle **16**, as illustrated in FIG. **3**D. FIG. **3**D illustrates a maximum angle **36** of pivoting, as protrusions **48** make contact with the ends of slots **28**, respectively. As shown in FIG. **3**E (enlarged view of the portion of FIG. **3**C identified within circle **3**E), protrusions **48** are centered in slots **28** when shaft **22** is aligned with the longitudinal axis L-L of the tulip **14**. Alternatively, slots **28** could be asymmetrically formed so as to allow angulation **36** on one side of the longitudinal axis L-L to be greater than angulation on the other side (angulation in the opposite direction).

In the embodiment shown, saddle **16** is a standard saddle and is configured and dimensioned to be retained by shoulder **14**S when fitted into tulip **14**, see FIG. **3**H. The saddle-shaped tulip **14** further includes a slot **14**ST passing therethrough, as shown in FIGS. **3**A and **3**H that is configured and dimensioned to receive an orthopedic rod or plate therein, in manners known in the art. Threading **14**X allows a set screw (not shown) or the like to be torqued against the rod/plate to fix it relative to the tulip **14**. The saddle **16** is configured to apply compression to the head **24** to lock an orientation of the fastener **12** relative to the tulip **14**, thereby even preventing the movement in the one plane that is otherwise allowed, and thus preventing movement in all planes, such as in a manner already previously described.

All components **12**,**14**,**16** and **48** of assembly **10** are preferably made of titanium. Alternatively, one or more components may be made of one or more alternative materials such as described in regard to previous embodiments. The uniplanar angulation of assembly **10** may vary, but preferably has a range of about eighty (80) degrees (twice angle **36**). The dimensions of the components will vary depending upon the location of the spine in which they are used, the size of the patient (e.g., pediatric vs. adult, male vs. female, etc.), etc. The outside diameter of tulip **14** typically falls within a range of about 8 mm to about 16 mm. The outside diameter of shaft **22** typically falls within a range of about 3 mm to about 10 mm. The length of shaft **22** typically falls within a range of about 10 mm to about 100 mm. The height **48**H of protrusion **48** is about 1 mm to about 2 mm, typically about 1.5 mm. The length **48**L: of protrusion **48** is about 1.5 mm to about 3 mm, typically about 2.25 mm.

FIG. **4**A is a plan view of a uniplanar surgical screw assembly **10** according to another embodiment of the present invention. FIG. **4**B shows assembly **10** having been rotated about its longitudinal axis L-L by ninety degrees, relative to the view shown in FIG. **4**A. The assembly **10** of the embodiment of FIGS. **4**A-**4**I includes a fastener **12** (see the isolated view of FIG. **4**G), a saddle-shaped tulip **14** (see the isolated view of FIG. **4**H), a saddle **16** (see the isolated view of FIG. **4**I) and only one protrusion **48** (see FIGS. **4**C-**4**F), in contrast to the pair of protrusions **48** employed in the embodiment of FIGS. **3**A-**3**I.

Fastener **12** includes an elongate shaft **22** having a proximal end and a distal end and a head **24** at the proximal end thereof. As shown, elongate shaft **22** is a screw shaft having threads **26** therealong. Head **24** includes a slot **28** that extends in a proximal-distal direction aligned with the longitudinal axis L-L.

The tulip **14** has a bore **32** therethrough that is dimensioned to allow the distal end of elongate shaft **12** to pass therethrough, but the cross-sectional dimension of the distal opening **32**D is smaller than the largest cross-sectional dimension of the head **24**, and thereby prevents passage of the head **24** therethrough, as illustrated in FIGS. **4**A-**4**E. Protrusion **48** is integral with tulip **14** and protrudes into the bore **32**, as illustrated in FIGS. **4**C-**4**F. Slot **28** is configured and dimensioned to receive the protruding end of protrusion **48**, to allow protrusion **48** to freely slide therein in the proximal distal direction, but to prevent movements in any other directions. Slot **28** is formed to allow protrusion **48** to slide only in a proximal-distal direction that permits pivoting of the shaft **22** relative to the tulip **14** in one plane only. FIG. **4**C shows a longitudinal sectional view of assembly **10** taken along line **4**C-**4**C of FIG. **4**A. FIGS. **4**A-**4**C illustrate the assembly **10** where the fastener **12** is aligned with the longitudinal axis L-L of the assembly **10** and tulip **14**. FIG. **4**D shows the longitudinal sectional view of FIG. **4**C, but after uniplanar pivoting of fastener **12**/shaft **22** relative to tulip **14** by an angle **36** (as shown by the angle **36** between the longitudinal axis L'-L' of the fastener **12** and the longitudinal axis L-L of the tulip **14**.

Saddle **16** is configured and dimensioned to be fixed relative to tulip **14** while abutting the proximal portion of head **24** as shown in FIG. **4**C. Saddle **16** has a concave distal surface **16**S configured and dimensioned as a bearing surface to allow the convex curvature of head **24** to slide relative thereto. Accordingly, as shaft **22** is pivots relative to tulip **14**, head **24** rotates against bearing surfaces of the tulip **14** and saddle **16**, as illustrated in FIG. **4**D. FIG. **4**D illustrates a maximum angle **36** of pivoting in one direction, as protrusion **48** makes contact with the end of slot **28**. As shown in FIG. **4**E, protrusion **48** is centered in slot **28** when shaft **22** is aligned with the longitudinal axis L-L of the tulip **14**. Alternatively, slot **28** could be asymmetrically formed so as to allow angulation **36** on one side of the longitudinal axis L-L to be greater than angulation on the other side (angulation in the opposite direction).

In the embodiment shown, saddle **16** is a standard saddle and is configured and dimensioned to be retained by shoulder **14**S when fitted into tulip **14**, see FIG. **4**H. The saddle-shaped tulip **14** further includes a slot **14**ST passing therethrough, as shown in FIGS. **2**A and **2**G that is configured and dimensioned to receive an orthopedic rod or plate therein, in manners known in the art. Threading **14**X allows a set screw (not shown) or the like to be torqued against the rod/plate to fix it relative to the tulip **14**. The saddle **16** is configured to apply compression to the head **24** to lock an orientation of the fastener **12** relative to the tulip **14**, thereby even preventing the movement in the one plane that is otherwise allowed, and thus preventing movement in all planes, such as in a manner described in previous embodiments.

All components **12**,**14**,**16** and **18** of assembly **10** are preferably made of titanium. One or more components may be made of an alternative material, like described in previous embodiments. The uniplanar angulation of assembly **10** may vary, but preferably has a range of about eighty (80) degrees (twice angle **36**). The dimensions of the components will vary depending upon the location of the spine in which they are used, the size of the patient (e.g., pediatric vs. adult, male vs. female, etc.), etc. The outside diameter of tulip **14** typically falls within a range of about 8 mm to about 16 mm. The outside diameter of shaft **22** typically falls within a range of about 3 mm to about 10 mm. The length of shaft **22** typically falls within a range of about 10 mm to about 100 mm. The height **18**H of insert **18** is about 1 mm to about 2 mm, typically about 1.5 mm. The length **18**L of insert **18** is about 1.5 mm to about 3 mm, typically about 2.25 mm.

FIG. **5**A is a plan view of a uniplanar surgical screw assembly **10**, according to another embodiment of the present invention. FIG. **5**E shows assembly **10** having been rotated about its longitudinal axis L-L by ninety degrees, relative to the view shown in FIG. **5**A. The assembly **10** of the embodiment of FIGS. **5**A-**5**J includes a fastener **12** (see the isolated view of FIG. **5**G), a saddle-shaped tulip **14** (see the isolated view of FIG. **5**H), a saddle **16** (see the isolated view of FIG. **5**I) and a pair of flat inserts **58** (see isolated view of a flat insert **58** in FIG. **5**J).

Fastener **12** includes an elongate shaft **22** having a proximal end and a distal end and a head **24** at the proximal end thereof. As shown, elongate shaft **22** is a screw shaft having threads **26** therealong. Head **24** includes a pair of flats **68** on an otherwise convex surface, typically an otherwise spherical surface. The surfaces of flats **68** are substantially parallel to one another as shown in FIGS. **5**C-**5**D.

The tulip **14** has a bore **32** therethrough that is dimensioned to allow the distal end of elongate shaft **12** to pass therethrough, but the cross-sectional dimension of the distal opening **32**D is smaller than the largest cross-sectional dimension of the head **24**, and thereby prevents passage of the head **24** therethrough, as illustrated in FIGS. **5**A-**5**B and **5**D-**5**F. Flat inserts **58** are received in receptacles **64** formed in tulip **14** as shown in FIGS. **5**C-**5**D, in an orientation, so that the flat surface **58**F of flat insert **58** interfaces with flat **68** of head **24**, as also shown in FIGS. **5**C-**5**D. The interaction between the flats **68** and flat sides **58**F prevents all pivoting of the shaft **22** relative to the tulip **14**, except for in one plane, that plane being parallel to the flats **68** and flat sides **58**F. The non-flat side of insert **58** is received in receptacle **64** which has a shape that mates with the non-flat side of the insert **58**.

The non-flat side of insert **58** is shaped and configured to prevent the flat insert **58** from sliding relative to the receptacle **64**. In the embodiment shown in FIG. **5**J, the non-flat side comprises a proximal end portion **58**P, a central portion **58**C, and a distal end portion **58**D, wherein the central portion **58**C extends further from the flat side **58**D than the distances by which the proximal **58**P and distal **58**D end portions extend from the flat side **58**F. In the embodiment shown in FIG. **5**J, the central portion has a first curvature and the proximal and distal end portions have a second curvature, the first curvature having a smaller radius of curvature than the second curvature. In the embodiment of FIG. **5**J, the non-flat side includes a bulbous portion **58**C extending further from the flat side than an extent to which a remainder (**58**Pm **58**D) of the non-flat side extends from the flat side **58**F.

Flat inserts **58** may be fixed to tulip **14** by adhesives, welding, press fitting and/or other fixation expedients, or loosely fit within tulip **14**. As shown in FIGS. **5**C-**5**D, flats **68** are formed diametrically opposite one another on head **24**, so as to be parallel to one another. This is necessary to allow the flats **68** to rotate relative to the flat inserts **58** as shaft **22** is pivoted relative to tulip **14**, such as is shown in FIG. **5**F. Thus, flats **68** and flat surface **58**F are all oriented in substantially parallel planes to maintain uniplanar movement of the shaft **22** relative to the tulip **14**.

FIG. **5**B shows a longitudinal sectional view of assembly **10** taken along line **5**B-**5**B of FIG. **5**E. FIGS. **5**A-**5**C illustrate the assembly **10** where the fastener **12** is aligned with the longitudinal axis L-L of the assembly **10** and tulip **14**. FIG. **5**F shows the longitudinal sectional view of FIG. **5**B, but after uniplanar pivoting of fastener **12**/shaft **22** relative to tulip **14** by an angle **36** (as shown by the angle **36** between the longitudinal axis L'-L' of the fastener **12** and the longitudinal axis L-L of the tulip **14**.

Saddle **16** is configured and dimensioned to be fixed relative to tulip **14** while abutting the proximal portion of head **24** as shown in FIG. **5**D. Saddle **16** has a concave distal surface **16***s* configured and dimensioned as a bearing surface to allow the convex curvature of head **24** to slide relative thereto. Accordingly, as shaft **22** is pivoted relative to tulip **14**, head **24** rotates against bearing surfaces of the tulip **14** and saddle **16**, as illustrated in FIG. **5**F. FIG. **5**F illustrates a maximum angle **36** of pivoting. The limits of pivoting are established by the shaft **22** contacting against the tulip **14**.

In the embodiment shown, saddle **16** is a standard saddle and is configured and dimensioned to be retained by shoulder **14**S when fitted into tulip **14**, see FIG. **5***h*. The saddle-shaped tulip **14** further includes a slot **14**ST passing therethrough, as shown in FIGS. **5**B and **5**H that is configured and dimensioned to receive an orthopedic rod or plate therein, in manners known in the art. Threading **14**X allows a set screw (not shown) or the like to be torqued against the rod/plate to fix it relative to the tulip **14**.

All components **12**,**14**,**16** and **58** of assembly **10** are preferably made of titanium. One or more components may be made of an alternative material such as described above. The uniplanar angulation of assembly **10** may vary, but preferably has a range of about 80 degrees (twice angle **36**). The dimensions of the components will vary depending upon the location of the spine in which they are used, the size of the patient (e.g., pediatric vs. adult, male vs. female, etc.), etc. The outside diameter of tulip **14** typically falls within a range of about

8 mm to about 16 mm. The outside diameter of shaft **22** typically falls within a range of about 3 mm to about 10 mm. The length of shaft **22** typically falls within a range of about 10 mm to about 100 mm. The length **58**L of insert **58** is about 4.5 mm to about 6.5 mm, typically about 5.3 mm.

FIG. **6**A is a plan view of a uniplanar surgical screw assembly **10**, according to another embodiment of the present invention. FIG. **6**E shows assembly **10** having been rotated about its longitudinal axis L-L by ninety degrees, relative to the view shown in FIG. **6**A. The assembly **10** of the embodiment of FIGS. **6**A-**6**J includes a fastener **12** (see the isolated view of FIG. **6**G), a saddle-shaped tulip **14** (see the isolated view of FIG. **6**H), a saddle **16** (see the isolated view of FIG. **6**I) and a single flat insert **58** (see isolated view of FIG. **5**J).

Fastener **12** includes an elongate shaft **22** having a proximal end and a distal end and a head **24** at the proximal end thereof. As shown, elongate shaft **22** is a screw shaft having threads **26** therealong. Head **24** includes a flat **68** on an otherwise convex surface, typically an otherwise spherical surface. The surface of flat **68** is substantially parallel to the longitudinal axis L'-L' of the fastener **12**, as shown in FIG. **6**G.

The tulip **14** has a bore **32** therethrough that is dimensioned to allow the distal end of elongate shaft **22** to pass therethrough, but the cross-sectional dimension of the distal opening **32**D is smaller than the largest cross-sectional dimension of the head **24**, and thereby prevents passage of the head **24** therethrough, as illustrated in FIGS. **6**A-**6**B and **6**D-**6**F. Flat insert **58** is received in receptacle **64** formed in tulip **14** as shown in FIGS. **6**C-**6**D, in an orientation, so that the flat surface **58**F of flat insert **58** interfaces with flat **68** of head **24**, as also shown in FIGS. **6**C-**6**D. The interaction between the flat **68** and flat side **58**F prevents all pivoting of the shaft **22** relative to the tulip **14**, except for in one plane, that plane being parallel to the flat **68** and flat side **58**F. The non-flat side of insert **58** is received in receptacle **64** which has a shape that mates with the non-flat side of the insert **58**.

The non-flat side of insert **58** is shaped and configured to prevent the flat insert **58** from sliding relative to the receptacle **64**. In the embodiment shown in FIG. **6**J, the non-flat side comprises a proximal end portion **58**P, a central portion **58**C, and a distal end portion **58**D, wherein the central portion **58**C extends further from the flat side **58**D than the distances by which the proximal **58**P and distal **58**D end portions extend from the flat side **58**F. In the embodiment shown in FIG. **6**J, the central portion has a first curvature and the proximal and distal end portions have a second curvature, the first curvature having a smaller radius of curvature than the second curvature. In the embodiment of FIG. **5**J, the non-flat side includes a bulbous portion **58**C extending further from the flat side than an extent to which a remainder (**58**Pm **58**D) of the non-flat side extends from the flat side **58**F.

Flat insert **58** may be fixed to tulip **14** by adhesives, welding, press fitting and/or other fixation expedients, or may be loosely fitted in tulip **14**. As shown in FIGS. **6**C-**6**D, the surface of flat **68** is parallel to the flat surface **58**F. This is necessary to allow the flat **68** to rotate relative to the flat insert **58** as shaft **22** is pivoted relative to tulip **14**, such as is shown in FIG. **6**F. Thus, flat **68** and flat surface **58**F are oriented in substantially parallel planes to maintain uniplanar movement of the shaft **22** relative to the tulip **14**.

FIG. **6**B shows a longitudinal sectional view of assembly **10** taken along line **6**B-**6**B of FIG. **6**E. FIGS. **6**A-**6**C illustrate the assembly **10** where the fastener **12** is aligned with the longitudinal axis L-L of the assembly **10** and tulip **14**. FIG. **6**F shows the longitudinal sectional view of FIG. **6**B, but after uniplanar pivoting of fastener **12**/shaft **22** relative to tulip **14** by an angle **36** (as shown by the angle **36** between the longitudinal axis L'-L' of the fastener **12** and the longitudinal axis L-L of the tulip **14**.

Saddle **16** is configured and dimensioned to be fixed relative to tulip **14** while abutting the proximal portion of head **24** as shown in FIG. **6**D. Saddle **16** has a concave distal surface **16***s* configured and dimensioned as a bearing surface to allow the convex curvature of head **24** to slide relative thereto. Accordingly, as shaft **22** is pivoted relative to tulip **14**, head **24** rotates against bearing surfaces of the tulip **14** and saddle **16**, as illustrated in FIG. **6**F. FIG. **6**F illustrates a maximum angle **36** of pivoting, as limited by the shaft contacting the tulip.

In the embodiment shown, saddle **16** is a standard saddle and is configured and dimensioned to be retained by shoulder **14**S when fitted into tulip **14**, see FIGS. **6**F and **6**H. The saddle-shaped tulip **14** further includes a slot **14**ST passing therethrough, as shown in FIGS. **6**E and **6**H that is configured and dimensioned to receive an orthopedic rod or plate therein, in manners known in the art. Threading **14**X allows a set screw (not shown) or the like to be torqued against the rod/plate to fix it relative to the tulip **14**.

All components **12**,**14**,**16** and **58** of assembly **10** are preferably made of titanium. One or more components may be made of an alternative material, such as described above with regard to previous embodiments. The uniplanar angulation of assembly **10** may vary, but preferably has a range of about 80 degrees (twice angle **36**). The dimensions of the components will vary depending upon the location of the spine in which they are used, the size of the patient (e.g., pediatric vs. adult, male vs. female, etc.), etc. The outside diameter of tulip **14** typically falls within a range of about 8 mm to about 16 mm. The outside diameter of shaft **22** typically falls within a range of about 3 mm to about 10 mm. The length of shaft **22** typically falls within a range of about 10 mm to about 100 mm. The length **58**L of insert **58** is about 4.5 mm to about 6.5 mm, typically about 5.3 mm.

FIG. **7**A is a plan view of a uniplanar surgical screw assembly **10**, according to another embodiment of the present invention. FIG. **7**B shows assembly **10** having been rotated about its longitudinal axis L-L by ninety degrees, relative to the view shown in FIG. **7**A. The assembly **10** of the embodiment of FIGS. **7**A-**7**I includes a fastener **12** (see the isolated view of FIG. **7**G), a saddle-shaped tulip **14** (see the isolated view of FIG. **7**H), and a saddle **16** (see the isolated view of FIG. **7**I).

Fastener **12** includes an elongate shaft **22** having a proximal end and a distal end and a head **24** at the proximal end thereof. As shown, elongate shaft **22** is a screw shaft having threads **26** therealong. Head **24** includes a pair of protrusions **78** extending from diametrically opposite sides of a convex surface. Protrusions **78** may be inserts fixed to head **24**, but are preferably integrally formed therewith.

The tulip **14** has a bore **32** therethrough that is dimensioned to allow the distal end of elongate shaft **12** to pass therethrough, but the cross-sectional dimension of the distal opening **32**D is smaller than the largest cross-sectional dimension of the head **24**, and thereby prevents passage of the head **24** therethrough, as illustrated in FIGS. **7**A-**7**E. Slots **88** are formed in the inner surface of tulip **14** as shown in FIG. **7**E. Slots **88** each extend in a proximal-distal direction and are formed diametrically opposite one another. Slots **88** are configured and dimensioned to receive the protruding ends of protrusions **78**, to allow protrusions **78** to freely slide therein in the proximal-distal directions, but to prevent movements in any other directions, i.e., only uniplanar pivoting is allowed. As noted, protrusions **78** are preferably integral with head **24**, but when fixed thereto, may be fixed to head **24** by adhesives, welding, press fitting and/or other fixation expedients, preferably by press fitting into receptacles formed in the head **24**. As shown in FIGS. **7**C-**7**F, slots **88** are formed diametrically opposite one another, separated by 180 degrees around the tulip **14**. This is necessary to allow both protrusions **78** to slide in the same plane, resulting in an assembly that allows the elongate shaft **22** to pivot relative to the tulip **14** in one plane only. FIG. **7**C shows a longitudinal sectional view of assembly **10** taken along line **7**C-**7**C of FIG. **7**A. FIGS. **7**A-**7**C illustrate the assembly **10** where the fastener **12** is aligned with the longitudinal axis L-L of the assembly **10** and tulip **14**. FIG. **7**D shows the longitudinal sectional view of FIG. **7**C, but after uniplanar pivoting of fastener **12**/shaft **22** relative to tulip **14** by an angle **36** (as shown by the angle **36** between the longitudinal axis L'-L' of the fastener **12** and the longitudinal axis L-L of the tulip **14**.

Saddle **16** is configured and dimensioned to be fixed relative to tulip **14** while abutting the proximal portion of head **24** as shown in FIG. **1**C. Saddle **16** has a concave distal surface **16**S configured and dimensioned as a bearing surface to allow the convex curvature of head **24** to slide relative thereto. Additionally, in this embodiment, saddle **16** includes a pair of diametrically opposed notches in the bottom surface thereof that are configured and dimensioned to slidably fit over the protrusions **78**.

As shaft **22** is pivoted relative to tulip **14**, head **24** rotates against bearing surfaces of the tulip **14** and saddle **16**, as illustrated in FIG. **7**D. FIG. **7**D illustrates a maximum angle **36** of pivoting, as protrusions **78** make contact with the ends of slots **88**, respectively. As shown in FIG. **7**E, protrusions **78** are centered in slots **88** when shaft **22** is aligned with the longitudinal axis L-L of the tulip **14**. Alternatively, slots **88** could be asymmetrically formed so as to allow angulation **36** on one side of the longitudinal axis L-L to be greater than angulation on the other side (angulation in the opposite direction).

In the embodiment shown, saddle **16** is configured and dimensioned to be retained by shoulder **14**S when fitted into tulip **14**, see FIGS. **7**E and **7**H. The saddle-shaped tulip **14** further includes a slot **14**ST passing therethrough, as shown in FIGS. **7**A and **7**H that is configured and dimensioned to receive an orthopedic rod or plate therein, in manners known in the art. Threading **14**X allows a set screw (not shown) or the like to be torqued against the rod/plate to fix it relative to the tulip **14**. The saddle **16** is configured to apply compression to the head **24** to lock an orientation of the fastener **12** relative to the tulip **14**, thereby even preventing the movement in the one plane that is otherwise allowed, and thus preventing movement in all planes.

All components **12**,**14**,**16** and **78** of assembly **10** are preferably made of titanium. One or more components may be made of an alternative material, like previous embodiments described above. The uniplanar angulation of assembly **10** may vary, but preferably has a range of about 80 degrees (twice angle **36**). The dimensions of the components will vary depending upon the location of the spine in which they are used, the size of the patient (e.g., pediatric vs. adult, male vs. female, etc.), etc. The outside diameter of tulip **14** typically falls within a range of about 8 mm to about 16 mm. The outside diameter of shaft **22** typically falls within a range of about 3 mm to about 10 mm. The length of shaft **22** typically falls within a range of about 10 mm to about 100 mm. The height **78**H of protrusion **78** is in the range from about 1 mm to about 3 mm, typically about 2 mm. The width **78**W of protrusion **78** is within a range of from about 1 mm to about 2.5 mm, typically about 1.75 mm.

FIG. **8**A is a plan view of a uniplanar surgical screw assembly **10**, according to another embodiment of the present invention. FIG. **8**B shows assembly **10** having been rotated about its longitudinal axis L-L by ninety degrees, relative to the view shown in FIG. **8**A. The assembly **10** of the embodiment of FIGS. **8**A-**8**I includes a fastener **12** (see the isolated view of FIG. **8**G), a saddle-shaped tulip **14** (see the isolated view of FIG. **8**H), and a saddle **16** (see the isolated view of FIG. **8**I).

Fastener **12** includes an elongate shaft **22** having a proximal end and a distal end and a head **24** at the proximal end thereof. As shown, elongate shaft **22** is a screw shaft having threads **26** therealong. Head **24** includes a single protrusion **78** extending from a side of a convex surface thereof. Protrusion **78** may be an insert fixed to head **24**, but is preferably integrally formed therewith.

The tulip **14** has a bore **32** therethrough that is dimensioned to allow the distal end of elongate shaft **22** to pass therethrough, but the cross-sectional dimension of the distal opening **32**D is smaller than the largest cross-sectional dimension of the head **24**, and thereby prevents passage of the head **24** therethrough, as illustrated in FIGS. **8**A-**8**E. A slot **88** is formed in the inner surface on one side of the tulip **14** as shown in FIG. **8**E. Slot **88** extends in a proximal-distal direction and is formed in a direction parallel to the longitudinal axis L-L. Slot **88** is configured and dimensioned to receive the protruding end of protrusion **78**, to allow protrusion **78** to freely slide therein in the proximal-distal directions, but to prevent movements in any other directions, i.e., only uniplanar pivoting is allowed. As noted, protrusion **78** is preferably integral with head **24**, but when fixed thereto, may be fixed to head **24** by adhesives, welding, press fitting and/or other fixation expedients, preferably by press fitting into receptacles formed in the head **24**. As shown in FIGS. **8**C-**8**F, slot **88** is formed to receive protrusion **78** therein, to allow protrusion **78** to slide in a plane, resulting in an assembly that allows the elongate shaft **22** to pivot relative to the tulip **14** in one plane only. FIG. **8**C shows a longitudinal sectional view of assembly **10** taken along line **8**C-**8**C of FIG. **8**A. FIGS. **8**A-**8**C illustrate the assembly **10** where the fastener **12** is aligned with the longitudinal axis L-L of the assembly **10** and tulip **14**. FIG. **8**D shows the longitudinal sectional view of FIG. **8**C, but after uniplanar pivoting of fastener **12**/shaft **22** relative to tulip **14** by an angle **36** (as shown by the angle **36** between the longitudinal axis L'-L' of the fastener **12** and the longitudinal axis L-L of the tulip **14**.

Saddle **16** is configured and dimensioned to be fixed relative to tulip **14** while abutting the proximal portion of head **24** as shown in FIG. **8**C. Saddle **16** has a concave distal surface **16**S configured and dimensioned as a bearing surface to allow the convex curvature of head **24** to slide relative thereto. Additionally, in this embodiment, saddle **16** includes a notch **90** in the bottom surface thereof that is configured and dimensioned to slidably fit over the protrusion **78**.

As shaft **22** is pivoted relative to tulip **14**, head **24** rotates against bearing surfaces of the tulip **14** and saddle **16**, as illustrated in FIG. **8**D. FIG. **8**D illustrates a maximum angle **36** of pivoting, as protrusion **78** makes contact with the end of slot **88**. As shown in FIG. **8**E, protrusion **78** is centered in slot **88** when shaft **22** is aligned with the longitudinal axis L-L of the tulip **14**. Alternatively, slot **88** could be asymmetrically formed so as to allow angulation **36** on one side of the longitudinal axis L-L to be greater than angulation on the other side (angulation in the opposite direction).

In the embodiment shown, saddle **16** is configured and dimensioned to be retained by shoulder **14**S when fitted into tulip **14**, see FIGS. **8**E and **8**H. The saddle-shaped tulip **14** further includes a slot **14**ST passing therethrough, as shown in FIGS. **8**A and **8**H that is configured and dimensioned to receive an orthopedic rod or plate therein, in manners known in the art. Threading **14**X allows a set screw (not shown) or the like to be torqued against the rod/plate to fix it relative to the tulip **14**. The saddle **16** is configured to apply compression to the head **24** to lock an orientation of the fastener **12** relative to the tulip **14**, thereby even preventing the movement in the one plane that is otherwise allowed, and thus preventing movement in all planes.

All components **12**,**14**,**16** and **78** of assembly **10** are preferably made of titanium. One or more components may be made of an alternative material such as described above with regard to previous embodiments. The uniplanar angulation of assembly **10** may vary, but preferably has a range of about 80 degrees (twice angle **36**). The dimensions of the components will vary depending upon the location of the spine in which they are used, the size of the patient (e.g., pediatric vs. adult, male vs. female, etc.), etc. The outside diameter of tulip **14** typically falls within a range of about 8 mm to about 16 mm. The outside diameter of shaft **22** typically falls within a range of about 3 mm to about 10 mm. The length of shaft **22** typically falls within a range of about 10 mm to about 100 mm. The height **78**H of protrusion **78** is in the range from about 1 mm to about 3 mm, typically about 2 mm. The width **78**W of protrusion **78** is within a range of from about 1 mm to about 2.5 mm, typically about 1.75 mm.

FIG. **9**A is a plan view of a uniplanar surgical screw assembly **10** according to another embodiment of the present invention. FIG. **9**B shows assembly **10** having been rotated about its longitudinal axis L-L by ninety degrees, relative to the view shown in FIG. **9**A. The assembly **10** of the embodiment of FIGS. **9**A-**9**I includes a fastener **12** (see the isolated view of FIG. **9**G), a saddle-shaped tulip **14** (see the isolated view of FIG. **9**H), and a saddle **16** (see the isolated view of FIG. **9**I). Rather than employing one or more inserts **18**, the embodiment of FIGS. **9**A-**9**I provides protrusions **98** integrally formed with saddle **16** and protruding inwardly, see FIGS. **9**E, **9**F and **9**I.

Fastener **12** includes an elongate shaft **22** having a proximal end and a distal end and a head **24** at the proximal end thereof. As shown, elongate shaft **22** is a screw shaft having threads **26** therealong. Head **24** includes a pair of slots **108** that extend in a proximal-distal direction aligned with the longitudinal axis L-L.

The tulip **14** has a bore **32** therethrough that is dimensioned to allow the distal end of elongate shaft **22** to pass therethrough, but the cross-sectional dimension of the distal opening **32**D is smaller than the largest cross-sectional dimension of the head **24**, and thereby prevents passage of the head **24** therethrough, as illustrated in FIGS. **9**A-**9**E. Slots **28** are configured and dimensioned to receive the protruding ends of protrusions **98**, to allow protrusions **98** to freely slide therein in the proximal-distal direction, but to prevent movements in any other directions. As shown in FIGS. **9**C-**9**F, slots **28** are formed diametrically opposite one another, separated by 180 degrees around the head **24**. This is necessary to allow both protrusions **98** to slide in the same plane, resulting in an assembly that allows the elongate shaft **22** to pivot relative to the tulip **14** in one plane only. FIG. **9**C shows a longitudinal sectional view of assembly **10** taken along line **9**C-**9**C of FIG. **9**A. FIGS. **9**A-**9**C illustrate the assembly **10** where the fastener **12** is aligned with the longitudinal axis L-L of the assembly **10** and tulip **14**. FIG. **9**D shows the longitudinal sectional view of FIG. **9**C, but after uniplanar pivoting of fastener **12**/shaft **22** relative to tulip **14** by an angle **36** (as shown by the angle **36** between the longitudinal axis L'-L' of the fastener **12** and the longitudinal axis L-L of the tulip **14**.

Saddle **16** is configured and dimensioned to be fixed relative to tulip **14** while abutting the proximal portion of head **24** as shown in FIG. **9**C. Saddle **16** has a concave distal surface **16**S configured and dimensioned as a bearing surface to allow the convex curvature of head **24** to slide relative thereto. Accordingly, as shaft **22** is pivoted relative to tulip **14**, head **24** rotates against bearing surfaces of the tulip **14** and saddle **16**, as illustrated in FIG. **9**D. FIG. **9**D illustrates a maximum angle **36** of pivoting, as protrusions **98** make contact with the ends of slots **208**, respectively. As shown in FIG. **9**E (enlarged view of the portion of FIG. **9**C identified within circle **9**E), protrusions **98** are centered in slots **208** when shaft **22** is aligned with the longitudinal axis L-L of the tulip **14**. Alternatively, slots **108** could be asymmetrically formed so as to allow angulation **36** on one side of the longitudinal axis L-L to be greater than angulation on the other side (angulation in the opposite direction).

In the embodiment shown, saddle **16** is configured and dimensioned to be retained by shoulder **14**S when fitted into tulip **14**, see FIGS. **9**E and **9**H. The saddle-shaped tulip **14** further includes a slot **14**ST passing therethrough, as shown in FIGS. **9**A and **9**H that is configured and dimensioned to receive an orthopedic rod or plate therein, in manners known in the art. Threading **14**X allows a set screw (not shown) or the like to be torqued against the rod/plate to fix it relative to the tulip **14**. The saddle **16** is configured to apply compression to the head **24** to lock an orientation of the fastener **12** relative to the tulip **14**, thereby even preventing the movement in the one plane that is otherwise allowed, and thus preventing movement in all planes.

All components **12**,**14** and **16** of assembly **10** are preferably made of titanium. Alternatively, one or more components may be made of an alternative material, like previous embodiments described. The uniplanar angulation of assembly **10** may vary, but preferably has a range of about 80 degrees (twice angle **36**). The dimensions of the components will vary depending upon the location of the spine in which they are used, the size of the patient (e.g., pediatric vs. adult, male vs. female, etc.), etc. The outside diameter of tulip **14** typically falls within a range of about 8 mm to about 16 mm. The outside diameter of shaft **22** typically falls within a range of about 3 mm to about 10 mm. The length of shaft **22** typically falls within a range of about 10 mm to about 100 mm. The height **18**H of insert **18** is about 1 mm to about 2 mm, typically about 1.5 mm. The length **18**L: of insert **18** is about 1.5 mm to about 3 mm, typically about 2.25 mm.

FIG. **11**A is a plan view of a uniplanar surgical screw assembly **10**, according to another embodiment of the present invention. FIG. **11**B shows assembly **10** having been rotated about its longitudinal axis L-L by ninety degrees, relative to the view shown in FIG. **11**A. The assembly **10** of the embodiment of FIGS. **11**A-**11**IJ includes a fastener **12** (see the isolated view of FIG. **11**I), a saddle-shaped tulip **14** (see the isolated view of FIG. **11**G), and a saddle **16** (see the isolated view of FIG. **11**H).

Fastener **12** includes an elongate shaft **22** having a proximal end and a distal end and a head **24** at the proximal end thereof. As shown, elongate shaft **22** is a screw shaft having threads **26** therealong. Head **24** includes a pair of opposing flats **68** on an otherwise convex surface, typically an otherwise spherical surface. The surfaces of flats **68** are substantially parallel to one another as shown in FIG. **11**F.

The tulip **14** has a bore **32** therethrough that is dimensioned to allow the distal end of elongate shaft **12** to pass therethrough, but the cross-sectional dimension of the distal opening **32**D is smaller than the largest cross-sectional dimension of the head **24**, and thereby prevents passage of the head **24** therethrough, as illustrated in FIGS. **11**A-**11**E. Saddle **16** includes a pair of opposing flats **158** (see FIG. **11**H) that interface with flats **68** (see FIG. **11**F). Saddle **16** is rotationally fixed relative to tulip **14** when assembly **10** is assembled (see FIG. **11**E). The interface between flats **158** and flats **68**, combined with the prevention of saddle **16** from rotating relative to tulip **14**, prevents all pivoting of the shaft **22** relative to the tulip **14**, except for in one plane, that plane being parallel to the flats **68** and flats **158**.

FIG. **11**C shows a longitudinal sectional view of assembly **10** taken along line **11**C-**11**C of FIG. **11**B. FIGS. **11**A-**11**C illustrate the assembly **10** where the fastener **12** is aligned with the longitudinal axis L-L of the assembly **10** and tulip **14**. FIG. **11**D shows the assembly **10** after uniplanar pivoting of fastener **12**/shaft **22** relative to tulip **14** by an angle **36** (as shown by the angle **36** between the longitudinal axis L'-L' of the fastener **12** and the longitudinal axis L-L of the tulip **14**.

Saddle **16** is configured and dimensioned to be fixed relative to tulip **14** while abutting the proximal portion of head **24** as shown in FIG. **11**E. Saddle **16** has a concave distal surface **16***s* configured and dimensioned as a bearing surface to allow the convex curvature of head **24** to slide relative thereto. Accordingly, as shaft **22** is pivoted relative to tulip **14**, head **24** rotates against bearing surfaces of the tulip **14** and saddle **16**, as illustrated in FIG. **11**D. FIG. **11**D illustrates a maximum angle **36** of pivoting. The limits of pivoting are established by the shaft **22** contacting against the tulip **14**.

In the embodiment shown, the saddle-shaped tulip **14** includes a slot **14**ST passing therethrough, as shown in FIGS. **11**A and **11**C that is configured and dimensioned to receive an orthopedic rod or plate therein, in manners known in the art (an example of which is shown in FIG. **10**). Threading **14**X allows a set screw **46** (see FIG. **10**) or the like to be torqued against the rod/plate to fix it relative to the tulip **14**.

All components **12**,**14** and **16** of assembly **10** are preferably made of titanium. One or more components may be made of an alternative material such as described above. The uniplanar angulation of assembly **10** may vary, but preferably has a range of about 80 degrees (twice angle **36**). The dimensions of the components will vary depending upon the location of the spine in which they are used, the size of the patient (e.g., pediatric vs. adult, male vs. female, etc.), etc. The outside diameter of tulip **14** typically falls within a range of about 8 mm to about 16 mm. The outside diameter of shaft **22** typically falls within a range of about 3 mm to about 10 mm. The length of shaft **22** typically falls within a range of about 10 mm to about 100 mm. The length of flat **158** is about 4.5 mm to about 6.5 mm, typically about 5.0 mm.

FIG. **11**J is a proximal end view of the assembly of FIG. **11**B illustrating a tool interface **16**T that can be interfaced by a tool to drive the fastener **12** into the bone. The present invention is not limited to this type of interface as any other equivalent type of torquing interface could be used.

FIG. **12**A is a plan view of a surgical screw assembly **10**, according to another embodiment of the present invention. In the embodiment of FIG. **12**A, the surgical screw assembly is a polyaxial surgical screw assembly, meaning that, in an unlocked condition, shaft **22** can pivot relative to tulip **14** in any plane. However, the locking force augmentation features (e.g., the step features, arrangement and functioning of the tulip and head, and methods of providing enhanced locking force) as described with this embodiment are equally applicable to uniplanar surgical screw assemblies, such as those described above, as well as screw assemblies that can pivot in multiple planes, but not all planes, and are generally applicable to all polyaxial and uniplanar screw assemblies to provide enhanced locking force. FIG. **12**B is a longitudinal sectional view of the assembly **10** taken along line **12**B-**12**B in FIG. **12**A. FIG. **12**C is a perspective view of the assembly **10** of FIG. **12**A.

The assembly **10** of the embodiment of FIGS. **12**A-**12**G includes a fastener **12** including an elongate shaft **22** and a head **24** at a proximal end of the shaft **22**. As shown, elongate shaft **22** is a screw shaft having threads **26** therealong. Head **24** is substantially spherical, having a convex external surface. A tulip **14** has a bore **32** therethrough that defines a bearing surface against which head **24** can rotate when assembly **10** is in an unlocked configuration. Bore **32** is dimensioned to allow the distal end of elongate shaft **12** to pass therethrough as well as to allow the head **24** to be inserted into the tulip **14**.

FIG. **12**D is an enlarged detailed view of the portion of FIG. **12**B within circle **12**D. A first step feature **40** is located at a distal end portion of bore **32** and extends inwardly therefrom. The first step feature **40** reduces the diameter **38** of bore **32** to a dimension **42** that allows the distal end of the elongate shaft to pass therethrough, and allows all of the shaft **22** to pass therethrough, but prevents passage of head **24** therethrough as a portion of the first step feature contacts the external surface of the head, as shown in FIG. **12**D. A second step feature **50** is located at a distal end portion of bore **32**, distally of first step feature **40**. Second step feature **50** further reduces the diameter of bore **32** to a dimension **52** less than dimension **42** established by first step feature, the further reduced dimension **52** allowing the distal end of the elongate shaft **22** to pass therethrough, and allows all of the shaft **22** to pass therethrough, but prevents passage of head **24** therethrough.

FIG. **12**D illustrates the assembly in an unlocked configuration. In an unlocked configuration, as noted above, head **24** can be rotated relative to tulip **14** so as to pivot the shaft **22** relative to the longitudinal axis L-L of the tulip **14**. As also noted above, in this embodiment, shaft **22** can be pivoted in any plane when assembly **10** is in an unlocked configuration. However, the step features described with regard to this embodiment can be likewise installed in a uniplanar assembly, wherein, in an unlocked configuration, shaft **22** would be allowed to pivot in a single plane only.

FIG. **12**E is a top view of the assembly **10** of FIG. **12**A. A tool interface **16**T is provided in the proximal end of head **24** that can be interfaced by a tool to drive the fastener **12** into the bone. The present invention is not limited to this type of interface as any other equivalent type of torquing interface could be used.

In the unlocked configuration shown in FIGS. **12**B and **12**D, the external surface of head **24** contacts the first step feature **40**. In a preferred embodiment, the external surface of head **24** does not contact the second step feature **50**, as shown in FIG. **12**D. Alternatively, step feature **50** may be configured to extend further into the bore **32** so that the external surface of head **24** contacts both the first and second step features when in an unlocked configuration.

FIG. **12**F is a longitudinal sectional view of the assembly **10**, similar to that shown in FIG. **12**B, but when the assembly **10** is in a locked configuration. FIG. **12**G is an enlarged detailed view of the portion of FIG. **12**F within circle **12**G. When in a locked configuration the external surface of the head **24** contacts both first step feature **40** and second step feature **50**. To establish a locked configuration, a compression force is established between head **24** and step features **40**, **50**. This is typically accomplished by applying force in a distal direction to the proximal end of head **24** while holding tulip **14** relatively stationary, applying force to tulip **14** in a proximal direction while holding head **24** relatively stationary, or most typically, applying force to head **24** in a distal direction while drawing tulip **14** in a proximal direction. Upon application of sufficient force (typically in the range of about 7.5 Nm to about 12.5 Nm, more typically in the range of about 9.5 Nm to 10.5 Nm, although the preferred force may vary depending upon the dimensions of the components and the materials from which they are made, for example) the external surface of the head **24** and step features **40**, **50** engage one another such that at least one of a portion of the external surface of the head **24** contacting the step feature **40** and step feature **40** deforms and typically a cold welding is performed, while at least frictional contact is established between the external surface of the head **24** and step feature **50** is established. Preferably, at least one of a portion of the external surface of the head **24** contacting step feature **50** and step feature **50** also deforms and established cold welding. This results in locking head **24** relative to tulip **14**, thereby preventing movements of head **24** relative to tulip **14**.

It is possible, if necessary to unlock the assembly **10** after a locking condition has been established. This can be accomplished by removal of the compression force, after which a tool can be inserted into bore **32** to pry tulip **14** free from head **24**, thereby breaking the cold welds, or by any other technique that breaks the cold welds, such as by proximal movement of head **24** relative to tulip **14** or distal movement of tulip **14** relative to head **24**.

Preferably step features **40** and **50** extend continuously about the entire inner circumference of bore **32** as illustrated in the schematic distal end view of tulip **14**. Alternatively, step features **40** and **50** may be discontinuously provided in various arrangements. FIG. **12**I illustrates an arrangement in which a pair of step features **40** and a pair of step features **50** extend from bore **32** and are diametrically opposed with one another, with step features **40** and **50** being aligned with one another in the longitudinal axis direction. FIG. **12**J illustrates an arrangement in which a pair of step features **40** and a pair of step features **50** extend from bore **32** and are diametrically opposed with one another, with step features **40** and **50** being offset to one another by ninety degrees. FIG. **12**K illustrates an arrangement in which a three step features **40** are equidistantly spaced about the circumference of bore **32** and three step features **50** are equidistantly spaced about the circumference of bore **32**, with respective features **40** and **50** being aligned in the longitudinal direction. Alternatively, features **40** may be offset from features **50** when viewed in the direction of the longitudinal axis L-L. FIG. **12**L illustrates an arrangement in which a pair of first step features **40** are diametrically opposed and six second step features **50** are equidistantly spaced about the circumference of bore **32**. Likewise, an embodiment could be provided with two step features **50** and six step features **40**. Further alternatively to continuous step features **40** and **50**, any number of discontinuous first step features **40** and any number of discontinuous second step features **50** may be provided, with any circumferential positioning (relative to the circumference of bore **32**) desired. Also, the step features **40** may be aligned longitudinally with the step features **50** and/or staggered.

Referring now back to FIGS. **12**D and **12**G, a preferred configuration of the first and second step features **40**,**50** is described. A proximal end portion **40**P that extends from the bore **32** is the portion of the step feature **40** that contacts the external surface of the head **24** and deforms and/or is deformed by head **24** during locking. Likewise, proximal end portion **50**P that extends from the bore **32** is the portion of the step feature **50** that contacts the external surface of the head **24** during locking and, in embodiments where deformation takes place, deforms and/or is deformed by head **24** during locking. A longitudinal surface **40**L of first step feature **40** extends distally away from proximal end portion **40**P and preferably extends tangentially and distally away from the external surface of head **24** when proximal portion **40**P contacts the external surface of the head **24**. Alternatively, the longitudinal surface **40**L may extend away from the external surface of the head **24** at some other angle, but preferably does not contact the external surface of the head **24** even in the locked configuration. A longitudinal surface **50**L of second step feature **50** extends distally away from proximal end portion **50**P and preferably extends tangentially and distally away from the external surface of head **24** when proximal portion **50**P contacts the external surface of the head **24**. Alternatively, the longitudinal surface **50**L may extend away from the external surface of the head **24** at some other angle, but preferably does not contact the external surface of the head **24** even in the locked configuration.

Referring to FIGS. **12**B, **12**C and **12**F, the tulip **14** includes a slot extending therethrough normal to the longitudinal axis L-L of bore **32**. Slot **14**ST is configured and dimensioned to receive a rod, shaft, plate or channel for connection to assembly **10**. A saddle **16** is configured and dimensioned to be fitted in the bore **32** of tulip **14** against the head **24** to prevent the head **24** from moving proximally relative to the tulip **14**. Saddle **16** is configured and dimensioned to be fixed relative to tulip **14** while abutting the proximal portion of head **24**. Saddle **16** has a concave distal surface **16**S configured and dimensioned as a bearing surface to allow the convex curvature of head **24** to slide relative thereto. Accordingly, as shaft **22** is pivoted relative to tulip **14**, head **24** rotates against bearing surfaces of the tulip **14**/bore **32** and saddle **16**. The limits of pivoting are established by the shaft **22** contacting against the tulip **14**. Threading **14**X in tulip **14** allows a set screw **46** (see FIG. **10**) or other driving member to be torqued or otherwise driven against the rod, shaft, plate or channel to fix it relative to the tulip **14**, and also to apply force to the saddle **16**, which in turn drives compression of the head **24** relative to the step features **40**, **50** to established a locked configuration. Thus, the saddle **16** is configured to apply compression to the head **24** to lock an orientation of the fastener **12** relative to the tulip **14**, by driving the external surface of the head **24** against the first and second step features **40**, **50**.

All components **12**,**14**, **16**, **40** and **50** of assembly **10** are preferably made of titanium. One or more components may be made of an alternative material such as cobalt chromium alloys, stainless steel, or any of the other alternative materials described above. The step features **40** and **50** are preferably integrally made with the tulip **14**, such as by machining metal sintering, direct metal deposition or casting. Alternatively, the step features **40**, **50** can be integrally attached to the tulip to extend from the bore **32** in the manners described, by welding, or some other permanent attachment method that will not release even when the proximal portions of the step features **40**, **50** are plastically deformed under the compression forces. The dimensions of the components will vary depending upon the location of the spine (or elsewhere in the body) in which they are used, the size of the patient (e.g., pediatric vs. adult, male vs. female, etc.), etc. The outside diameter of tulip **14** typically falls within a range of about 8 mm to about 16 mm. The outside diameter of shaft **22** typically falls within a range of about 3 mm to about 10 mm. The length **22**L of shaft **22** typically falls within a range of about 10 mm to about 100 mm. The inside diameter **38** of bore **32** is typically within the range of about 3 mm to about 11.5 mm. The inside diameter **38** in the embodiment shown in FIG. **12**D is about 8.1 mm and the inside diameter **38** in the embodiment shown in FIG. **12**G is about 9.6 mm. The outside diameter of head **24** is typically within the range of about 2.5 mm to about 11.5 mm. The outside diameter of head **24** in the embodiment shown in FIG. **12**D is about 7.5 mm and the outside diameter of head **24** in the embodiment shown in FIG. **12**G is about 9 mm. Dimension **52** is typically in the range of about 5 mm to about 10 mm, more typically in the range of about 6 mm to about 9 mm. In one preferred embodiment, dimension **52** was about 7.05 mm. In another preferred embodiment, dimension **52** was about 8.55 mm Dimension **42** is typically in the range of about 5.3 mm to about 10.3 mm, more typically in the range of about 6.3 mm to about 9.3 mm However, the dimensions **42** and **52** may vary from these ranges, as dimensions of **38** and the outside diameter of head **24** vary. In one preferred embodiment, where dimension **52** was about 7.05 mm, dimension **42** was about 7.35 mm. In another preferred embodiment, where dimension **52** was about 8.55 mm, dimension **42** was about 8.85 mm. The tolerance between head **24** and bore **32** is typically in the range of about 0.3 mm to about 0.9 mm. The tolerance in the embodiments of FIGS. **12**D and **12**G is about 0.6 mm±0.05 mm.

FIG. **13**A is a plan view of a surgical screw assembly **10**, according to another embodiment of the present invention. In the embodiment of FIG. **13**A, the surgical screw assembly is a polyaxial surgical screw assembly, meaning that, in an unlocked condition, shaft **22** can pivot relative to tulip **14** in any plane. However, the locking force augmentation features (e.g., the step features, arrangement and functioning of the tulip and head, and methods of providing enhanced locking force) as described with this embodiment are equally applicable to uniplanar surgical screw assemblies, such as those described above, as well as screw assemblies that can pivot in multiple planes but not all planes, and generally to all polyaxial and uniplanar screw assemblies to provide enhanced locking force. FIG. **13**B is a longitudinal sectional view of the assembly **10** taken along line **13**B-**13**B in FIG. **13**A. FIG. **13**C is a perspective view of the assembly **10** of FIG. **13**A.

The assembly **10** of the embodiment of FIGS. **13**A-**13**G includes a fastener **12** including an elongate shaft **22** and a head **24** at a proximal end of the shaft **22**. As shown, elongate shaft **22** is a screw shaft having threads **26** therealong. Head **24** is substantially spherical, having a convex external surface. A tulip **14** has a bore **32** therethrough that defines a bearing surface against which head **24** can rotate when assembly **10** is in an unlocked configuration. Bore **32** is dimensioned to allow the distal end of elongate shaft **12** to pass therethrough as well as to allow the head **24** to be inserted into the tulip **14**.

FIG. **13**D is an enlarged detailed view of the portion of FIG. **13**B within circle **13**D. A first step feature **40** is located at a distal end portion of bore **32** and extends inwardly therefrom. The first step feature **40** reduces the diameter **38** of bore **32** to a dimension **42** that allows the distal end of the elongate shaft to pass therethrough, and allows all of the shaft **22** to pass therethrough, but prevents passage of head **24** therethrough as a portion of the first step feature contacts the external surface of the head, as shown in FIG. **13**D. A second step feature **50** is located at a distal end portion of bore **32**, distally of first step feature **40**. Second step feature **50** further reduces the diameter of bore **32** to a dimension **52** less than dimension **52** established by first step feature, the further reduced dimension **52** allowing the distal end of the elongate shaft **22** to pass therethrough, and allows all of the shaft **22** to pass therethrough, but prevents passage of head **24** therethrough. Third step feature **60** further reduces the diameter of bore **32** to a dimension **62** less than dimension **52** established by second step feature, the further reduced dimension **62** allowing the distal end of the elongate shaft **22** to pass therethrough, and allowing all of the shaft **22** to pass therethrough, but preventing passage of head **24** therethrough.

FIG. **13**D illustrates the assembly in an unlocked configuration. In an unlocked configuration, as noted above, head **24** can be rotated relative to tulip **14** so as to pivot the shaft **22** relative to the longitudinal axis L-L of the tulip **14**. As also noted above, in this embodiment, shaft **22** can be pivoted in any plane when assembly **10** is in an unlocked configuration. However, the step features described with regard to this embodiment can be likewise installed in a uniplanar assembly, wherein, in an unlocked configuration, shaft **22** would be allowed to pivot in a single plane only; or in an otherwise limited assembly, such as an assembly allowing pivoting in more than one plane, but not all planes.

FIG. **13**E is a top view of the assembly **10** of FIG. **13**A. A tool interface **16**T is provided in the proximal end of head **24** that can be interfaced by a tool to drive the fastener **12** into the bone. The present invention is not limited to this type of interface as any other equivalent type of torquing interface could be used.

In the unlocked configuration shown in FIGS. **13**B and **13**D, the external surface of head **24** contacts the first step feature **40**, see the enlarged partial view in FIG. **13**F, taken of the portion of FIG. **13**D within ellipse **13**F. In a preferred embodiment, the external surface of head **24** does not contact the second step feature **50** or the third step feature **60**, as shown in FIG. **13**F. Alternatively, step feature **50** may be configured to extend further into the bore **32** so that the external surface of head **24** contacts both the first and second step features **40**, **50** when in an unlocked configuration. Further alternatively, step features **50** and **60** may be configured to extend further into the bore **32** so that the external surface of head **24** contacts first step feature **40**, second step feature **50** and third step feature **60** when in an unlocked configuration. However, in these alternative arrangements, final locking would be even more enhanced relative to the embodiment described in FIG. **13**F.

FIGS. **13**G-**13**K correspond to FIGS. **13**A-**13**E, except that the assembly s shown in a provisionally locked configuration. FIG. **13**H is a longitudinal sectional view of the assembly **10** taken along line **13**H-**13**H in the plan view of FIG. **13**G.

FIG. **13**I is a perspective view of the assembly **10** shown in FIG. **13**G. FIG. **13**J is an enlarged detailed view of the portion of FIG. **13**H within circle **13**J. When in a provisionally locked configuration the external surface of the head **24** contacts both first step feature **40** and second step feature **50**, but preferably not step feature **60**, as shown in FIG. **13**L.

FIGS. **13**M-**13**Q correspond to FIGS. **13**A-**13**E and **13**G-**13**K, respectively, except that the assembly is shown in a finally locked configuration. FIG. **13**N is a longitudinal sectional view of the assembly **10** taken along line **13**N-**13**N in the plan view of FIG. **13**M. FIG. **13**O is a perspective view of the assembly **10** shown in FIG. **13**M. FIG. **13**P is an enlarged detailed view of the portion of FIG. **13**N within circle **13**P. When in a finally locked configuration, the external surface of the head **24** contacts first step feature **40**, second step feature **50** and third step feature **60**, as shown in FIG. **13**R, a detailed partial view of the portion of FIG. **13**P within ellipse **13**R.

The step features of the present invention are designed to increase strength and stability of the locking forces applied between tulip **14** and head **24**. Polyaxial grip of the tulip **14** on the head **24** is enhanced. To establish a locked configuration, a compression force is established between head **24** and tulip **14**. This is typically accomplished by applying force in a distal direction to the proximal end of head **24** while holding tulip **14** relatively stationary, applying force to tulip **14** in a proximal direction while holding head **24** relatively stationary, or most typically, applying force to head **24** in a distal direction while drawing tulip **14** in a proximal direction. Upon application of sufficient force (typically in the range of about 4.0 Nm to about 7.0 Nm, more typically in the range of about 5.0 Nm to 6.0 Nm, although the preferred force may vary depending upon the dimensions of the components, the materials from which they are made and whether provisional locking or final locking is intended, for example) the external surface of the head **24** and step features **40**, **50**, **60** (or only **40** and **50**, for provisional locking) engage one another such that at least one of a portion of the external surface of the head **24** contacting the step feature **40** and step feature **40** partially deforms and typically a slight cold welding results. Likewise, at least one of a portion of the external surface of the head **24** contacting the step feature **50** and step feature **50** partially deforms and typically a slight cold welding results, resulting in provisional locking of the assembly (i.e., provisional locking of head **24** and fastener **12** relative to tulip **14**). Upon application of more force, typically in the range of about 7.5 NM to about 12.5 Nm, more typically in the range of about 9.5 Nm to 10.5 Nm, at least one of a portion of the external surface of the head **24** contacting step feature **60** and step feature **60** also partially deforms and establishes additional (further augmented) cold welding, resulting in final locking of the head **24**/fastener **12** relative to tulip **14**, thereby providing enhanced polyaxial grip of the head by the tulip, as compared to the amount of polyaxial grip provided during provisional locking. This prevents movements of head **24** relative to tulip **14** even after completion of an implantation and vertebral derotation procedure and enables the locking configuration that the assembly is placed in to be maintained after completion of the procedure.

It is possible, if necessary to unlock the assembly **10** after a provisional or final locking condition has been established. This can be accomplished by removal of the compression force, after which a tool can be inserted into bore **32** to pry tulip **14** free from head **24**, thereby breaking the cold welds, or by any other technique that breaks the cold welds, such as by proximal movement of head **24** relative to tulip **14** or distal movement of tulip **14** relative to head **24**.

Preferably step features **40**, **50** and **60** extend continuously about the entire inner circumference of bore **32**, like that described above with regard to two-step feature embodiments. However, any or all of step features **40**, **50** and **60** may be discontinuously provided in various arrangements. Any number of discontinuous first step features **40**, any number of discontinuous second step features **50** and any number of discontinuous third step features **60** may be provided, with any circumferential positioning (relative to the circumference of bore **32**) desired. Also, the step features **40**, **50** and **60** may be aligned longitudinally with one another and/or staggered.

Referring now back to FIGS. **13**F, **13**L and **13**R, a preferred configuration of the first, second and third step features **40**,**50**, **60** is described. A proximal end portion **40**P that extends from the bore **32** is the portion of the step feature **40** that contacts the external surface of the head **24** and deforms and/or is partially deformed by head **24** during locking. Likewise, proximal end portion **50**P that extends from the bore **32** is the portion of the step feature **50** that contacts the external surface of the head **24** during locking and partially deforms and/or is partially deformed by head **24** during locking, and proximal portion **60**P that extends from the bore **32** is the portion of the step feature **60** that contacts the external surface of the head and partially deforms and/or is partially deformed by head **24** during final locking. A longitudinal surface **40**L of first step feature **40** extends distally away from proximal end portion **40**P and preferably extends tangentially and distally away from the external surface of head **24** when proximal portion **40**P contacts the external surface of the head **24**. Alternatively, the longitudinal surface **40**L may extend away from the external surface of the head **24** at some other angle, but preferably does not contact the external surface of the head **24** even in the locked configuration. A longitudinal surface **50**L of second step feature **50** extends distally away from proximal end portion **50**P and preferably extends tangentially and distally away from the external surface of head **24** when proximal portion **50**P contacts the external surface of the head **24**. Alternatively, the longitudinal surface **50**L may extend away from the external surface of the head **24** at some other angle, but preferably does not contact the external surface of the head **24** even in the locked configuration. A longitudinal surface **60**L of third step feature **60** extends distally away from proximal end portion **60**P and preferably away from the external surface of the head **24** at some angle relative to the longitudinal axis of the bore **32**. In FIG. **13**R surface **50**L angles toward the center of bore **32** in a proximal to distal direction. Alternatively, surface **60**L may extend tangentially and distally away from the external surface of head **24** when proximal portion **60**P contacts the external surface of the head **24**. In any case, surface **60**L that is distal to portion **60**P preferably does not contact the external surface of the head **24** even in the finally locked configuration, see FIG. **13**R.

Referring to FIGS. **13**B, **13**H and **13**N, the tulip **14** includes a slot extending therethrough normal to the longitudinal axis L-L of bore **32**. Slot **14**ST is configured and dimensioned to receive a rod, shaft, plate or channel for connection to assembly **10**. A saddle **16** is configured and dimensioned to be fitted in the bore **32** of tulip **14** against the head **24** to prevent the head **24** from moving proximally relative to the tulip **14**. Saddle **16** is configured and dimensioned to be fixed relative to tulip **14** while abutting the proximal portion of head **24**. Saddle **16** has a concave distal surface **16**S configured and dimensioned as a bearing surface to allow the convex curvature of head **24** to slide relative thereto. Accordingly, as shaft **22** is pivoted relative to tulip **14**, head **24** rotates against bearing surfaces of the tulip **14**/bore **32** and saddle **16**. The limits of pivoting are established by the shaft **22** contacting against the tulip **14**. Threading **14**X in tulip **14** allows a set screw **46** (see FIG. **10**) or other driving member to be torqued or otherwise driven against the rod, shaft, plate or channel to fix it relative to the tulip **14**, and also to apply force to the saddle **16**, which in turn drives compression of the head **24** relative to the step features **40**, **50**, **60** to establish a finally locked configuration, or against step features **40**, **50** to establish a provisionally locked configuration. Thus, the saddle **16** is configured to apply compression to the head **24** to lock an orientation of the fastener **12** relative to the tulip **14**, by driving the external surface of the head **24** against the first and second step features **40**, **50** (as well as step feature **60** in the finally locked configuration).

All components **12**,**14**, **16**, **40**, **50** and **60** of assembly **10** are preferably made of titanium. One or more components may be made of an alternative material such as cobalt chromium alloys, stainless steel, or any of the other alternative materials described above. The step features **40**, **50** and **60** are preferably integrally made with the tulip **14**, such as by machining, metal sintering, direct metal deposition or casting. Alternatively, the step features **40**, **50**, **60** can be integrally attached to the tulip to extend from the bore **32** in the manners described, by welding, or some other permanent attachment method that will not release even when the proximal portions of the step features **40**, **50**, **60** are plastically deformed under the compression forces. The dimensions of the components will vary depending upon the location of the spine (or elsewhere in the body) in which they are used, the size of the patient (e.g., pediatric vs. adult, male vs. female, etc.), etc. The outside diameter of tulip **14** typically falls within a range of about 8 mm to about 16 mm. The outside diameter of shaft **22** typically falls within a range of about 3 mm to about 10 mm. The length **22**L of shaft **22** typically falls within a range of about 8 mm to about 100 mm. The inside diameter **38** of bore **32** is typically within the range of about 3 mm to about 11.5 mm. In the embodiment shown in FIGS. **13**D, **13**J and **13**P, the inside diameter **38** is about 8.1 mm. In the embodiment shown in FIG. **12**G, the inside diameter is about 9.6 mm. The outside diameter of head **24** is typically within the range of about 2.5 mm to about 11.5 mm. In the embodiment shown in FIGS. **13**D, **13**J and **13**P, the outside diameter of head **24** is about 7.5 mm. Dimension **52** is typically in the range of about 2 mm to about 11 mm, more typically in the range of about 6 mm to about 9 mm. In one preferred embodiment, dimension **52** was about 7.05 mm. In another preferred embodiment, dimension **52** was about 8.55 mm. Dimension **42** is typically in the range of about 2.3 mm to about 11.3 mm, more typically in the range of about 6.3 mm to about 9.3 mm. Dimension **62** is typically in the range of about 1.7 mm to about 10.7 mm, more typically in the range of about 5.7 mm to about 8.7 mm However, the dimensions **42**, **52** and **62** may vary from these ranges, as dimensions of **38** and the outside diameter of head **24** vary. In one preferred embodiment, where dimension **52** was about 7.05 mm, dimension **42** was about 7.35 mm and dimension **62** was about 6.75 mm. In another preferred embodiment, where dimension **52** was about 8.55 mm, dimension **42** was about 8.85 mm and dimension **62** was about 8.25 mm. The tolerance between head **24** and bore **32** is typically in the range of about 0.3 mm to about 0.9 mm. In the embodiments of FIGS. **13**D, **13**J and **13**P, the tolerance is about 0.6 mm±0.05 mm.

The present invention described with regard to the embodiments of FIGS. **13**A-**13**Q provides capabilities that are not present in currently available polyaxial and uniplanar fastener assemblies. Not only can the fasteners **10** described in these embodiments be connected to a rod, the rod, shaft, plate or channel while allowing compression or distraction between vertebrae during a procedure, but they can also be provisionally locked with sufficient polyaxial grip in a provisional locking configuration, to allow tulip **14** to be levered with sufficient force to perform a derotation manipulation of a vertebra that the fastener is attached to, without disrupting the locked orientation of the tulip **14** relative to the head **24**, but allowing the tulip **14** to rotate relative to the rod, that it is connected to. This is described in further detail below.

FIGS. **14**A-**14**N illustrate steps that may be performed in carrying out a surgical procedure to correct spinal deformities such as scoliosis. The present invention is not limited to treatment of scoliosis, but is useful in surgical procedure used to treat other spinal deformities, diseases, etc. and can also be used for hard tissues of the body other than the vertebrae.

FIG. **14**A illustrates the spinal column **2** and rib cage **3** of a patient suffering from Adolescent Idiopathic Scoliosis (AIS) exhibiting a Lenke 1 Curve. Using fasteners **10** of the embodiment of FIGS. **13**A-**13**R, significant coronal plane correction can be consistently obtained. True axial plane correction can be achieved to address the rotational deformity of the spine **2**, ribs **3** and chest wall of the patient **1**. One of the deformities of the spine **2** in FIG. **1** that can be observed in FIG. **14**A is that the spine **2** has a curvature such it presents a concave curvature **2**C on the left side **50** and a convex curvature **2**X on the right side.

After installation of fastener assemblies **10** into the vertebrae of the spine (see FIG. **14**A), a rod **150** is implanted on the concave **2**C side, see FIG. **14**B. It is noted that all vertebrae that will need to be derotated have fasteners **10** of the type described with regard to the embodiment of FIGS. **13**A-**13**R and/or monoaxial fasteners, (preferably with extended reduction tabs **14**T, e.g., see FIGS. **15**A-**15**C, if planning to perform a rod translation technique, in the concave **2**C side, although in some cases tabs **14**T will not be necessary) but that other types of monoaxial, uniplanar or polyaxial fasteners could be used in locations where derotation is not necessary, if such locations exist. Rod **150** is inserted into the slots **14**S of the distal most and proximal most fasteners **10** and the set screw **46** of the proximal most fastener **10**P tightened to lock the rod. This locking is a provisional locking if performing the classical Cotrel & Debussy "CD" rod rotation technique described in the following two paragraphs, but is a final locking if performing a rod translation technique. The set screw **46** of the distal most fastener **10**D is tightened with a provisional locking force and then partially untightened, thereby provisionally locking fastener **2**D, while leaving the rod **150** in the correct sagittal plane.

Rod clamps **200** (available from SpineCraft, LLC, Westchester, Ill.) are used to rotate the rod **150** into the tulips **14** (slots **14**ST) of the apical fasteners (fasteners **10** attached to the pedicles of the vertebrae intermittent of the proximal most and distal most fasteners), see the posterior view (FIG. **14**C) and distal view (FIG. **14**D). Once the rod **150** has been inserted into a slot **14**ST, set screw **46** is installed so as to maintain the capture of the rod **150** in the tulip. The set screws **46** of the apical fasteners **10** are installed—torqued with a force sufficient to provisionally lock the apical fasteners in a manner described above, and then partially untightened to allow free rotation of the tulips **14** around the rod **150** during vertebral body derotation maneuvers described below.

At FIGS. **14**G-**14**H, the rod clamps are used to counter-rotate the rod **150** by an amount equal and opposite to the amount that it was rotated in FIGS. **14**E-**14**F so as to return the rod **150** to its position in **14**B, while at the same time bringing the spine **2** into sagittal alignment. By comparing FIGS. **14**G and **14**A, it can be observed that the spine **2** is now relatively straight in the sagittal plane, with the convex **2**X and concave **2**C curvatures having been substantially removed. Even through the spine **2** is now substantially correctly aligned in the sagittal plane, it is often the case that one or more vertebrae can still be rotated relative to its normal position, such that the spinous process **2**SP is not vertical (12 O'clock position) when viewed in the transverse plane (like the view in FIG. **14**J). In order to correct this type of deformity, a rotation of the abnormally oriented vertebra/vertebrae is/are needed.

In FIGS. **14**I-**14**J, derotator posts **302** (available from SpineCraft, LLC, Westchester, Ill.) are attached to the tulips **14** (for example, by having the prongs on the sides of the derotator posts **302** to interface with and lock to the QUAD RECESSES **14**Q in the tulips **14**, e.g. see FIGS. **13**M and **15**A, of the apical fasteners **10**, and opposing posts **302** that are attached to the same vertebra are connected by a transverse link **304** (available from SpineCraft, LLC, Westchester, Ill.). A handle **306** is attached to one or more of the derotator posts **302** of each derotator **300** (pair of posts connected by transverse link) to provide additional leverage for applying torque. Derotational torque (leverage) is then applied to each vertebra needing to be rotated by application of force to handles **306** This derotational torque (leverage) can be applied sequentially or simultaneously to all vertebrae needing to be derotated, but typically, the preferred approach is to use a combination of both, i.e., sequential rotation is applied to partially derotate, followed by en bloc derotation for final correction, to arrange the vertebrae properly such that the spinous processes **2**SP are substantially vertically aligned as in FIG. **14**J. The spine **2** is thus derotated, reducing rib prominence on the convex side and restoring coronal alignment of the spine **2**.

Fasteners **10** attached to the vertebrae to be rotated are placed in the provisional locking configuration prior to vertebral body derotation. This is accomplished by torqueing the set screws **46** to apply a provisional locking force that is typically about half of the amount of force used to finally lock the fasteners. Once axial alignment has been achieved through derotation as described, the set screws **46** are further torqued to apply the full force needed to place the fasteners **10** on the concave side in the final locking configuration, see FIG. **14**K. There is typically no need for compression and/or distraction at the levels of the apical vertebrae, but if this is required, alternate level/side sequential loosening to the provisionally locked fasteners **10** and then final locking is performed respectively before and after the segmental compression/distraction, see FIG. **14**K. Fastener **10** of FIGS. **13**A-**13**R, when in the provisional locking configuration, maintains the fastener **10** in a locked state, even after the force applied by the set screw **46** has been removed, due to the deformation of the components in contact (head **24** and step features **40**, **50**) and resulting cold welding. For this reason, the set screws **46** can be loosened after placing the fasteners **10** into the provisional locking configuration, but still maintained by the threads **14**X of the tulip **14**. This maintains capture of the rod **150**, while at the same time allowing relative rotation between the tulips **14** and the rod **150** during derotation, and while maintaining the orientational relationship between each tulip **14** and its respective head **24**. In the provisional locking configuration, the tulip **14** can withstand a levering force of about 100 to about 200 Newtons, typically about 150 Newtons, without breaking loose of the head **24** and thus still maintaining polyaxial grip, such that the fastener **10** moves as a unit and the tulip **14** does not rotate relative to the head **24**. Once the derotation is completed, the set screws **46** on the concave side are tightened to the final locking configuration to maintain the rotational positions of the tulips **14** relative to the shaft **150**. In the final locking configuration, the tulip **14** can withstand a levering force of about 350 to about 550 Newtons, typically about 450 Newtons, without breaking loose of the head **24** and thus still maintaining polyaxial grip, such that the fastener **10** remains fixed in its orientation and the tulip **14** does not rotate relative to the head **24** or the rod **150**.

After tightening the set screws **46** on the concave side, the derotator assemblies **300** are removed and a second rod **150** is implanted on the convex side, see FIG. **14**L, the fasteners **10** on the convex side then being placed in the provisional locking configuration by application of force through torqueing the respective set screws **46**.

Next, the spine **2** is compressed or distracted as needed (FIG. **14**M) according to known techniques, after which the set screws are re-torqued with sufficient force to place all fasteners into the final locking configuration. Cross connectors **400** (available from SpineCraft, LLC, Westchester, Ill.) are then attached to the rods **150** at or near their extremities, see FIG. **14**N, and the procedure is completed according to known practices.

FIGS. **15**A-**15**E illustrate a fastener **10** with extended reduction tabs **14**T according to an embodiment of the present invention. FIGS. **15**A-**15**E depict a fastener **10** of the type shown in FIGS. **12**A-**12**E, except that the tulip **14** and channel **32** have been extended by reduction tabs **14**T that extend proximally from the proximal end of tulip **14** as it is shown in FIG. **12**A. It is noted that extended reduction tabs **14**T are not limited to modification of the embodiment of FIGS. **12**A-**12**E, but can be likewise provided on any of the embodiments described herein, as well as on any tulip of any monoaxial, uniplanar, multi-planar or polyaxial fastener.

FIG. **15**A is a plan view of the surgical screw assembly **10** with reduction tabs **14**T. In the embodiment of FIG. **15**A, the surgical screw assembly is a polyaxial surgical screw assembly, meaning that, in an unlocked condition, shaft **22** can pivot relative to tulip **14** in any plane. However, the locking force augmentation features (e.g., the step features, arrangement and functioning of the tulip and head, and methods of providing enhanced locking force) as described with this embodiment are equally applicable to uniplanar surgical screw assemblies, such as those described above, as well as screw assemblies that can pivot in multiple planes but not all planes, and generally to all polyaxial and uniplanar screw assemblies to provide enhanced locking force.

Reduction tabs **14**T are integrally provided to extend from the main body of tulip **14**. Alternatively, reduction tabs **14**T can be joined to tulip **14** by welding or other equivalent attachment means, provided that the reduction tabs **14**T can be readily separated from the main body tulip **14**, such as by breaking them off. In the embodiment shown in FIG. **15**A, reduction tabs **14**T are formed integrally with tulip **14** by machining, metal sintering, direct metal deposition or casting or the like. A weakened section such as neck region **14**N is provided at the junction of each reduction tab **14**T with the main body of the tulip **14**, to facilitate readily breaking off the reduction tabs **14**T from tulip **14** thereby separating them. A reduction fastener **10** is used in situations such as when a vertebra has been pushed forward (anteriorly slipped) such that it resides at a lower level than the rest of the vertebrae when the patient is lying on his/her stomach. In these situations, a fastener **10** without reduction tabs **14**T, when installed into such a vertebra, becomes oriented such that the rod **150** cannot reach the slot **14**ST to be received therein so that the driver **46** can be installed into the slot **14**ST and driven against the rod **150** to draw up the vertebra. To remedy this, extended reduction tab fastener **10** includes reduction tabs **14**T that extend the slot **14**EST so that the slot reaches the rod **150**, and allows rod **150** to be received therein sufficiently to install driver **46** on top of rod **150** to be driven against the rod **150** and draw up the vertebra.

FIG. **15**B is a longitudinal sectional view of the assembly **10** taken along line **15**B-**15**B in FIG. **15**A. FIG. **15**C is a perspective view of the assembly **10** of FIG. **15**A. FIGS. **15**B-C illustrate that there are two reduction tabs **14**T, one on each side of slot **14**EST. Of course, some other number of reduction tabs **14**T could be provided, so long as they adequately function to extend the slot **14**EST, to draw up the vertebra as described, and are readily removable. In the embodiment shown in FIG. **15**B, reduction tabs **14**T extend the slot **14**ST to form extended slot **14**EST which is more than twice as long as slot **14**ST of FIG. **12**A or the slot formed solely by the main body of the tulip **14** in FIG. **15**B. Reduction tabs **14**T typically have a length selected from the range of about 10 mm to about 200 mm, more typically from the range of about 15 mm to about 125 mm Reduction tabs **14**T are provided with threading **14**X that cooperates continuously with the threading **14**X in the slot **14**ST of the main body of the tulip **14**. In this way, driver **46** can be seamlessly threaded through the reduction tabs **14**T and into the main body of the tulip **14**, as the vertebra is drawn up and the main body of the tulip **14** is drawn over the rod **150** such that rod **150** is received in the slot **14**ST of the main body of the tulip **14**. Once this has been accomplished, the reduction tabs **14**T can be broken off from the tulip and removed from the surgical site.

The assembly **10** of the embodiment of FIGS. **15**A-**15**E includes a fastener **12** including an elongate shaft **22** and a head **24** at a proximal end of the shaft **22**. As shown, elongate shaft **22** is a screw shaft having threads **26** therealong. Head **24** is substantially spherical, having a convex external surface. A tulip **14** has a bore **32** therethrough that defines a bearing surface against which head **24** can rotate when assembly **10** is in an unlocked configuration. Bore **32** is dimensioned to allow the distal end of elongate shaft **12** to pass therethrough as well as to allow the head **24** to be inserted into the tulip **14**.

FIG. **15**D is an enlarged detailed view of the portion of FIG. **15**B within circle **15**D. A first step feature **40** is located at a distal end portion of bore **32** and extends inwardly therefrom. The first step feature **40** reduces the diameter **38** of bore **32** to a dimension **42** that allows the distal end of the elongate shaft to pass therethrough, and allows all of the shaft **22** to pass therethrough, but prevents passage of head **24** therethrough as a portion of the first step feature contacts the external surface of the head, as shown in FIG. **15**D. A second step feature **50** is located at a distal end portion of bore **32**, distally of first step feature **40**. Second step feature **50** further reduces the diameter of bore **32** to a dimension **52** less than dimension **42** established by first step feature **40**, the further reduced dimension **52** allowing the distal end of the elongate shaft **22** to pass therethrough, and allows all of the shaft **22** to pass therethrough, but prevents passage of head **24** therethrough.

FIG. **15**E is a top view of the assembly **10** of FIG. **15**A. A tool interface **16**T is provided in the proximal end of head **24** that can be interfaced by a tool to drive the fastener **12** into the bone. The present invention is not limited to this type of interface as any other equivalent type of torquing interface could be used.

While the present invention has been described with reference to the specific embodiments thereof, it should be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the true spirit and scope of the invention. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process step or steps, to the objective, spirit and scope of the present invention. All such modifications are intended to be within the scope of the claims appended hereto.

That which is claimed is:

1. A surgical screw assembly comprising:

a fastener including an elongate shaft having a proximal end and a distal end and a head at said proximal end, said head having an external surface;

a tulip having a tulip proximal end portion, a tulip distal end portion, an external surface and an internal bearing surface, said tulip distal end having a bore therethrough defining said internal bearing surface and having a diameter dimensioned to allow said distal end of said elongate shaft to pass therethrough; and

locking enhancement features configured to cooperate with said head;

wherein, in an unlocked configuration, said head is movable relative to said tulip and said locking enhancement features, and contacts a first subset of said locking enhancement features but does not contact a second subset of said locking enhancement features; in a provisionally locked configuration, said locking enhancement features engage said head with a first polyaxial grip strength; and in a finally locked configuration, said locking enhancement features engage said head with a second polyaxial grip strength, said second polyaxial grip strength being greater than said first polyaxial grip strength.

2. The assembly of claim **1**, wherein said first subset and said second subset of said locking enhancement features contact said head in said provisionally locked configuration; and wherein said first subset, said second subset and a third subset of said locking enhancement features contact said head in said finally locked configuration.

3. The assembly of claim **1**, wherein said fastener is placed in said provisionally locked configuration by applying a provisional locking compression force between said head and said tulip.

4. The assembly of claim **3**, wherein said fastener is maintained in said provisionally locked configuration after removal of said provisional locking compression force.

5. The assembly of claim **4**, wherein, when implanted in a vertebra of a spine of a patient, when in said provisionally locked configuration, and when said provisional locking compression force has been removed, said provisionally locked configuration has sufficient locking strength to prevent relative movement between said tulip and said head when said tulip is driven to cause rotation of the vertebra.

6. The assembly of claim **1**, wherein said fastener is placed in said finally locked configuration by applying a final locking compression force between said head and said tulip, wherein said final compression force is greater than a provisional locking compression force required to place said fastener in said provisionally locked configuration.

7. The assembly of claim **1**, wherein said locking enhancement features are integral with said tulip.

8. The assembly of claim **1**, wherein said locking enhancement features extend inwardly from said internal bearing surface.

9. The assembly of claim **1**, wherein said locking enhancement features comprise:

a first step feature located at a distal end portion of said bore and extending inwardly from said bore, said first step feature reducing the diameter of said bore to allow said distal end of said elongate shaft to pass therethrough, but prevent passage of said head therethrough as a portion of said first step feature contacts said head; and

a second step feature located at a distal end portion of said bore, distally of said first step feature, said second step feature further reducing the diameter of said bore to a dimension less than a dimension established by said first step feature, the further reduced diameter allowing said distal end of said elongate shaft to pass therethrough, but preventing passage of said head therethrough as a portion of said second step feature contacts said head and a portion of said first step feature contacts said head.

10. The assembly of claim **9**, wherein said locking enhancement features further comprise a third step feature located at a distal end portion of said bore, distally of said second step feature, said third step feature still further reducing the diameter of said bore to a dimension less than a dimension established by said second step feature, the still further reduced diameter allowing said distal end of said elongate shaft to pass therethrough, but preventing passage of said head therethrough as a portion of said third step feature contacts said head, a portion of said second step feature contacts said head and a portion of said first step feature contacts said head.

11. The assembly of claim **1**, further comprising a driving member configured to engage a proximal end portion of said tulip and to establish a compression force between said locking enhancement features and said head.

12. The assembly of claim **1**, wherein said tulip further comprises a slot through said proximal end portion extending transverse to said bore, said slot configured to receive a support member; wherein when the support member is received in said slot, when in said provisionally locked configuration, said tulip is prevented from movement relative to said head, but is rotatable relative to the support member; and, wherein in said finally locked configuration, said tulip is prevented from movement relative to said head and is prevented from movement relative to the support member.

13. The assembly of claim **12**, further comprising reduction tabs extending proximally of said tulip and extending said slot.

14. The assembly of claim **1**, further comprising a saddle, said saddle being configured and dimensioned to be fitted in said tulip proximally of and against said head.

15. A method of operating a surgical screw assembly, said method comprising:

providing a surgical screw assembly comprising: a fastener including an elongate shaft having a proximal end and a distal end and a head at said proximal end, said head having an external surface; a tulip having a tulip proximal end portion, a tulip distal end portion, an external surface and an internal bearing surface, said tulip distal end having a bore therethrough defining said internal bearing surface and having a diameter dimensioned to allow said distal end of said elongate shaft to pass therethrough; and locking enhancement features configured to cooperate with said head; wherein, in an unlocked configuration, said tulip is free to rotate relative to said head and contacts a first subset of said locking enhancement features but does not contact a second subset of said locking enhancement features;

attaching a support member to said assembly;

applying a first compression force between said tulip and said locking enhancement features, wherein said locking enhancement features engage with said head to place said assembly in a provisionally locked configuration;

wherein, in said provisionally locked configuration, said tulip is prevented from rotating relative to said head, but said tulip is movable relative to the support member.

16. The method of claim **15**, wherein said fastener further comprises reduction tabs extending proximally from said tulip, and wherein said attaching a support member comprises positioning the support member between the reduction tabs, relatively moving the fastener and the support member toward one another so that the support member is positioned within the tulip, and removing the reduction tabs from the tulip after said attaching a support member to said assembly.

17. The method of claim **15**, further comprising relatively rotating one of the support member and said tulip relative to the other, while said provisionally locked configuration prevents said tulip from rotating relative to said head.

18. The method of claim **15**, further comprising removing the first compression force, whereby said assembly is maintained in said provisionally locked configuration after said removing the first compression force.

19. The method of claim **15**, further comprising:

applying a second compression force greater than said first compression force between said tulip and said locking enhancement features, wherein said locking enhancement features engage with said head in a finally locked configuration;

wherein, in said finally locked configuration, said tulip is prevented from rotating relative to said head, and said tulip is prevented from moving relative to the support member.

20. A method of using a surgical screw assembly in a surgical procedure, said method comprising:

providing a surgical screw assembly comprising: a fastener including an elongate shaft having a proximal end and a distal end and a head at said proximal end, said head having an external surface; a tulip having a tulip proximal end portion, a tulip distal end portion, an external surface and an internal bearing surface, said tulip distal end having a bore therethrough defining said internal bearing surface and having a diameter dimensioned to allow said distal end of said elongate shaft to pass therethrough; and locking enhancement features configured to cooperate with said head; wherein, in an unlocked configuration, said tulip is free to rotate relative to said head and contacts a first subset of said locking enhancement features but does not contact a second subset of said locking enhancement features;

implanting said shaft into a vertebra of a patient;

attaching a support member to said assembly;

applying a first compression force between said tulip and said locking enhancement features, wherein said locking enhancement features engage with said head to place said assembly in a provisionally locked configuration; and

applying a force to said tulip to rotate the vertebra relative to the support member, and rotating said tulip and the vertebra relative to the support member while said tulip is prevented from rotating relative to said shaft.

21. The method of claim **20**, further comprising:

when the vertebra has been rotated to a desired orientation, applying a second compression force greater than said first compression force between said tulip and said locking enhancement features, while maintaining the desired orientation, wherein said locking enhancement features engage with said head to place said assembly in a finally locked configuration, the vertebra is prevented from rotating relative to the support member and said tulip is prevented from rotating relative to the support member.

22. The method of claim **20**, further comprising:

applying a second force to said tulip to drive the vertebra toward or away from an adjacent vertebra.

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